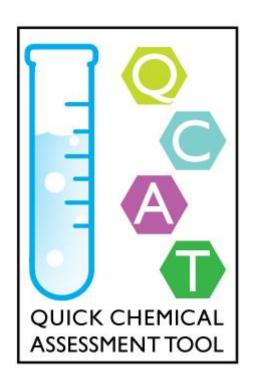


Quick Chemical Assessment Tool Version 2.0



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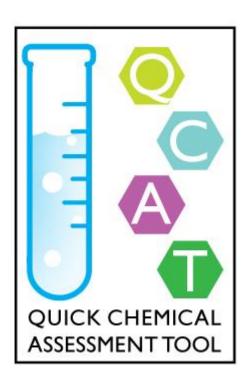
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Disclaimer:

Although the Quick Chemical Assessment Tool is based on methodology developed by the United States Environmental Protection Agency's (EPA) Design for the Environment (DfE) program subsequently adapted by Clean Production Action as the GreenScreenTM, this should not be taken as an endorsement of the Quick Chemical Assessment Tool by either organization. The Quick Chemical Assessment Tool remains the product of the Washington State Department of Ecology who is responsible for its contents and implementation.

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Quick Chemical Assessment Version 2.0



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A note from the author

Here are some suggestions that may improve your experience with this tool.

- 1. Print the list of abbreviations (<u>Appendix 11</u>) and keep it handy. QCAT is based on data from governments and authoritative bodies from around the world. The names and terms are often large and varied and the list is extensive. You will reference it often.
- 2. Take advantage of automation. Since QCAT was created, data from authoritative sources have been automated in databases such as Pharos and ChemHat. While QCAT still allows users to review the original source data, many of the automated systems are continually updated so reviewing source data are no longer necessary. If you have access to Pharos, use it as your first choice since it is updated regularly. If you don't have access to Pharos, ChemHAT is an excellent alternative. In addition, Ecology created a grading tool, which can help you determine the results of your assessment.
- 3. Use the Checklist (<u>Appendix 10</u>). This checklist will help you identify what data may be found from the different sources. If you use Pharos or ChemHAT, you can indicate what data were found in those sources. If you go to the original sources, the checklist will help you keep track of what sites you visited and what information you found.
- 4. Document your findings clearly. Transparency is fundamental to the chemical hazard assessment process. QCAT includes a blank template (<u>Appendix 6</u>) to report your results. It also includes an example of a completed QCAT (<u>Appendix 7</u>) to show how results are currently reported. While the assessor has considerable flexibility on how the results are reported, it must be clear to reviewers how the chemical was categorized and what data was used in the assessment.
- 5. Expect links to break. Like any internet-based methodology, links will change. This is particularly true for Step II sources that have not been automated. Be prepared to do an internet search and don't be surprised if some sources disappear. This version had to remove one Step II source as it was no longer supported. This happened with a previous version as well. Expect it!
- 6. Check for updates. Although QCAT is intended to be complete, Ecology will post changes to any part of QCAT that might affect use of the tool in between version revisions. Before you start, compare the date for this version and check Ecology's QCAT web page (http://www.ecv.wa.gov/GreenChemistry/QCAT.html) for important updates.
- 7. You must have a CAS Number. QCAT is based on finding chemical data based on a Chemical Abstract Services (CAS) Number. If you don't have a CAS Number, QCAT will probably not work for you!

1. Introduction

As concern has increased about the widespread use of toxic chemicals in products and the overall effect these chemicals have upon human health and the environment, issues have arisen around the replacement of these chemicals of concern with safer alternatives. There have been several instances where chemicals of concern were replaced with chemicals shown to pose an equal or greater hazard than the original. This process is called 'regrettable substitution.'

One well-documented example of regrettable substitution is the replacement of chlorinated solvents in the auto repair industry with hexane. (CDC, 2001) In response to increasing regulation of methylene chloride and other halogenated solvents, several manufacturers switched from chlorinated solvents to hexane for products, such as brake cleaners. They did this without first determining if any hazards were associated with the substitute. Hexane was known to cause nerve damage as early as 1964. (Yamada, 1964) A few years after the substitution, workers in auto repair shops in California began to report health concerns that were eventually tied to hexane. (Berkeley, 2010) Examples like this emphasize the need for methodologies to compare chemicals of concern with potential substitutes to guarantee that products are both toxic free and safe for use.

The U.S. Environmental Protection Agency (EPA) took the early lead in this field and established the Design for the Environment (DfE¹) program in the late 1990s. DfE pioneered work in the field of alternatives assessments by developing a series of hazard criteria used to compare chemicals of concern with potential substitutes. DfE revised the hazard criteria in 2011, and they formed the basis of the methodology DfE used in its alternatives assessment program. (DfE, 2011)

In addition, DfE established a voluntary program with several manufacturers of consumer products and, by comparing these criteria, created the DfE labeling program. This program was renamed and rebranded in 2015 into Safer Choice. Ingredients in Safer Choice labeled products have undergone extensive review by the program. Each ingredient in the formulation has the lowest possible impact on human health and the environment in their functional class while maintaining product functionality at a reasonable cost. Since the inception of the labeling program, more than 2,500 products carry the Safer Choice label. (DfE, 2014) In addition to the Safer Choice Label program, the program developed a <u>Safer Chemical Ingredient List</u> (SCIL), grouped by function.

Other organizations have taken the DfE hazard criteria and alternatives assessment process and adapted them for use by a wider audience. A non-profit organization, Clean Production Action (CPA) was one of the earliest adopters. CPA adapted the DfE criteria and methodology and created the <u>GreenScreen® for Safer Chemicals</u> (GS®), a tool that emphasizes transparency during the chemical hazard assessment (CHA) process. (CPA, 2012) CPA tested the new GS® methodology by conducting an alternatives assessment of the flame retardant, decabromodiphenyl ether. (CPA, 2007) Several companies and organizations, including the Washington Department of Ecology (Ecology), have adopted the GS® as a tool for conducting CHAs in their alternatives assessment processes.

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¹ This and many other abbreviations commonly used in QCAT are listed in Appendix 11.

Ecology used the GS^{\circledast} to assess the use of decabromodiphenyl ether in electronic enclosures and residential upholstered furniture. (Ecology, 2009) Other organizations also using the GS^{\circledast} include Green Chemistry and Commerce Council (GC3, 2012) and Hewlett-Packard (Lavoie, 2010).

Although this tool provides the highest degree of certainty against a regrettable substitution, a GreenScreen® requires a high level of technical expertise and resource allocation. These limitations make it very difficult for small and medium businesses with limited resources and expertise to conduct any degree of alternatives assessment. For this reason, Ecology developed the Quick Chemical Assessment Tool (QCAT).

The QCAT is based on the GS® although it is neither as comprehensive nor as detailed in its evaluation. The objective is to provide a simpler tool that smaller businesses can use with at least some degree of assurance that they are not replacing one toxic chemical with another already identified as having hazard concerns. Because the QCAT is less comprehensive than the GS®, there is a greater risk of making a regrettable substitution than if a full GS® is conducted. Given that limitation, the QCAT has three primary advantages. QCAT:

- 1. Increases familiarity with CHAs, one step in the alternatives assessment process.
- 2. Helps identify chemicals that are clearly poor substitutes.
- 3. Helps dedicate limited resources to a more comprehensive alternatives assessment on the alternatives that look most promising.

As mentioned above, CHAs are only part of an alternatives assessment process. Other factors such as performance, cost, availability, exposure, and other variables may affect the viability of alternatives. The Interstate Chemicals Clearinghouse (IC2) published an <u>Alternative Assessment Guide</u> (AA Guide) in 2014. (IC2, 2014) The guide describes recommended AA processes, including three frameworks and ten modules to consider during development of an AA. The GS® and QCAT are included as different levels within the CHA module of the IC2 AA Guide. The National Academy of Sciences subsequently released <u>A Framework to Guide Selection of Chemical Alternatives</u> (NAS, 2014) which identifies CHAs as an important step in the alternatives assessment process.

Since the QCAT is based on the GS[®], we will first provide an overview of the GS[®], followed by a detailed description of the QCAT, how it is similar and different from the GS[®], and how to use it.

2. GreenScreen® Background

The GS® evaluates chemicals of concern and potential degradation by-products against a wide range of toxicity, environmental fate, and physical/chemical endpoints to determine safer alternatives. Chemicals receive a benchmark score based on the combination of the hazard assessments of 19 endpoints (18 required and 1 optional):

Hazard Criteria Endpoints

Human Health Effects Group I Group II Acute Mammalian Toxicity (AT) Carcinogenicity (C) Mutagenicity & Genotoxicity (M) Systemic Toxicity & Organ Effects Reproductive Toxicity (R) (including Immunotoxicity) (ST) Developmental Toxicity Neurotoxicity (N) (including Developmental Neurotoxicity) (D) Sensitization: Skin (SnS) Sensitization: Respiratory (SnR) Endocrine Activity (E) Irritation/Corrosivity: Skin (IrS) Irritation/Corrosivity: Eyes (IrE)

Environmental Health

- Acute Aquatic Toxicity (AA)
- Chronic Aquatic Toxicity (CA)
- Other Ecotoxicity Studies (Eo), when available (optional except for Benchmark 4)

Environmental Fate

- Persistence (P)
- Bioaccumulation (B)

Physical/Chemical Properties

- Reactivity (R)
- Flammability (F)

The GS^{\otimes} requires a high level of technical expertise. Specialists in toxicology, chemistry, computer modeling, and other scientific areas generate data, evaluate sources, review technical information, and assign benchmark scores to the chemicals that have undergone the screening process. This is particularly true when information from peer-reviewed journal articles and computer modeling is used to provide data for hazard endpoints.

The $GS^{\$}$ also requires a commitment of time and resources and therefore, is costly to implement. To address these concerns, the $GS^{\$}$ coordinates with other regulatory requirements ($GHS^{,2}$ REACH, 3 etc.) and uses authoritative lists to provide established criteria for those chemicals for which toxicity concerns have already been identified. This enables different individuals and organizations to implement the $GS^{\$}$ and reach similar conclusions, i.e., consistent results from different individuals and/or organizations

² The United Nation's Global Harmonization System. GHS requires labeling of chemicals for a wide range of hazard criteria.

³ The European Union's Registration Evaluation and Authorisation of Chemicals legislation. REACH establishes data requirements for any chemical manufactured or imported into the European Union.

performing an assessment on the same chemical using 'professional judgment.' If data are not available using easily accessible sources requiring little user interpretation, more technical sources requiring a higher level of interpretation are used to provide a complete data set for comparison.

As with many aspects of the GS^{\circledast} , the level of expertise required to evaluate data and determine whether it can be used increases as the data sources become more technical and detailed. Individuals with specialized degrees may be needed such as toxicologists, chemists, $(Q)SAR^4$ specialists, etc. to provide a professional evaluation of specific sources. For example, Ecology commissioned SRC (formerly Syracuse Research Corporation) to collect data and generate (Q)SAR data addressing hazard endpoints and other toxicity data for Ecology's chemical action plan (CAP) on the polybrominated diphenyl ether (PBDE) family of flameretardants. (Ecology, 2006) The data was subsequently used in the deca-BDE alternatives assessment. (Ecology, 2009)

Based on this detailed scientific evaluation, the GS® assessment process provides the highest degree of certainty that the CHA is valid and comprehensive. Because of the evolving nature of science, some degree of uncertainty will exist for any hazard evaluation methodology including the GS®. All chemicals and products should be subjected to periodic review to evaluate the impact of improvements in data and scientific understanding on the classification of chemicals and the final benchmark assigned from a particular evaluation.

The GS® places chemicals along a continuum of concern and assigns each chemical one of four possible benchmarks (Table 1):

Table 1: Benchmarks from the GS® Assessment Process

| Benchmark 4 | Few concerns, i.e., safer chemical | Preferable | | | |
|-------------|------------------------------------|--------------------------|--|--|--|
| Benchmark 3 | Slight concern | Improvement possible | | | |
| Benchmark 2 | Moderate concern | Use but search for safer | | | |
| Benchmark 1 | High concern | Avoid | | | |

This benchmarking process identifies chemicals as safer alternatives to existing chemicals of concern. It also emphasizes the removal of chemicals of high concern (Benchmark 1) from the manufacturing stream and product design. Benchmark 1 chemicals are typically one or more of the following:

- 1. Persistent, bioaccumulative, and toxic (PBT).
- 2. Very persistent and very bioaccumulative (vPvB).
- 3. Identified as a high level hazard for a priority human health effect such as CMR (carcinogenicity, mutagenicity, or toxic for reproduction), etc.

Based on this analysis, safer alternatives to chemicals of concern are identified in a clear and reproducible manner.

⁴ (Q)SAR = Quality Structure Activity Relationships. (Q)SARs are computer modeling results that predict the toxicity of chemicals based upon structural similarities with chemicals possessing known toxicity concerns.

3. Quick Chemical Assessment Tool

Because of the high level of technical and resource commitments required by the $GS^{\$}$, a simpler assessment program called the Quick Chemical Assessment Tool (QCAT) has been developed by Ecology. The primary goal of the QCAT is to assign an appropriate grade for a chemical using a subset of high priority hazard endpoints identified in the $GS^{\$}$ and fewer data sources. This information provides an approximation of the concerns associated with chemicals, based on the limited data used in the evaluation process.

Because a QCAT assessment is based on fewer data, chemicals with concerns could be missed during the evaluation process. In other words, the degree of uncertainty associated with the QCAT assessment is greater than with a GS® review. In a GS® assessment, data are obtained and evaluated for each of 19 hazard endpoints. QCAT assessments examine nine of these hazard endpoints, which include priority human health effects (six endpoints), persistence, bioaccumulation, and acute aquatic toxicity. These nine endpoints identify a level of concern for each chemical.

The QCAT provides a quick and easy method to identify chemicals that are equally or more toxic than the chemical being reviewed. Limited resources can quickly identify chemicals that are not viable safer alternatives to the chemical of concern. Because of the reduced amount of information assessed, a QCAT does not identify preferable alternatives to the chemical of concern. If resources are limited, QCAT can be used to eliminate non-viable alternatives and remaining resources can be used to investigate the chemicals that pass a QCAT review.

The QCAT places chemicals along a continuum of concern and assigns each chemical one of four possible grades (Table 2):

| Table 2: Grade I | AVAIS from | n the OCAT | Assassment | Process |
|------------------|------------|--------------|---------------|---------|
| Table 2. Grade i | evers iron | II IIIE GGAI | ASSESSILIELLI | FILLESS |

| Grade A | Few concerns, i.e., safer chemical | Preferable |
|---------|------------------------------------|--------------------------|
| Grade B | Slight concern | Improvement possible |
| Grade C | Moderate concern | Use but search for safer |
| Grade F | High concern | Avoid |

The QCAT grading system is substantively different from the GS^{\circledast} benchmarking system. The differences emphasize that the QCAT is not as comprehensive as the GS^{\circledast} and that the risk of assigning an incorrect grade is greater. The QCAT clearly identifies Grade F (red) chemicals that should be targeted for removal from the manufacturing stream.

A secondary use of the QCAT is to assist users with the prioritization of chemicals. The QCAT identifies chemicals of concern and that information could be used to prioritize chemicals at a particular manufacturing facility to be assessed for a more detailed review, such as a GS® assessment. These chemicals of concern are separate from others that do not require immediate attention.

Evaluating chemicals using the QCAT provides several advantages. The QCAT focuses on important hazard endpoints, lowers data requirements, and provides a significant amount of information with a relatively low investment of resources in comparison to a GS® assessment. There are disadvantages of performing a QCAT rather than a GS® assessment. With its focus on a few endpoints, not all hazard endpoints are evaluated. An endpoint of concern could be overlooked either because the screening assessments did not highlight the endpoint or because new data are available that have not yet been reviewed by key information sources.

For example, new carcinogenicity data may be available on a chemical that has not yet been reviewed by the International Agency for Research on Cancer (IARC) or EPA. A GS® would include more recent information missed by the QCAT. The QCAT also provides less breadth and depth in evaluating data to determine levels of concern for hazard endpoints. Thus, performing a GS® assessment using a comprehensive weight of evidence approach with all available data may result in a different level of concern being assigned than by a QCAT.

Lastly, as more hazard information becomes available via the implementation of such regulations as the European Union's REACH and the Global Harmonization System, data may be available that was not used in the QCAT evaluation. This new data may alter the conclusions reached; therefore, users should revisit QCAT evaluations periodically and update them as necessary. Even with its limitations, the QCAT is a useful initial step in assessing chemical alternatives.

A. Use of Chemical Abstract Services (CAS) Number(s)

The QCAT is based on the Chemical Abstracts Service's (CAS) numbers. CAS numbers are assigned by the American Chemical Society and are unique to a specific chemical. Although a chemical may have many different common or product names, it typically has only one CAS number. Occasional errors do occur and, although a few chemicals may have more than one CAS identifier, it should have minimal impact on the QCAT assessment process.

CAS numbers reduce confusion caused by varying and numerous chemical names. CAS numbers may be readily available from the chemical supplier. If a CAS number is not readily available, it may be obtained from the Hazardous Substances Database (HSDB), the Registry of Toxic Effects of Chemical Substances (RTECS), or other authoritative sources. Information on these three sources is available in Appendix 2. If unsuccessful, the CAS number may be obtained from an internet search. Without a CAS number, a specific chemical cannot undergo assessment.

B. QCAT Hazard Endpoints

Specific hazard endpoints used in QCAT are a subset of those used in the GS[®] (<u>Table 3</u>). With the exception of endocrine activity, the QCAT hazard endpoints are the most widely studied and likely to be reported in QCAT data sources. QCAT prioritizes five categories of compounds:

- 1. Carcinogenic, mutagenic, and reproductive toxic compounds (CMRs)
- 2. Persistent, bioaccumulative, and toxic compounds (PBTs)
- 3. Acute environmental toxic compounds (acute aquatic toxicity)

- 4. Worker health and safety (acute mammalian toxicity)
- 5. Endocrine active compounds (developmental and reproductive)

Although authoritative data on endocrine activity are scarce, current research suggests endocrine active compounds have widespread negative impact on human health and the environment and, therefore, warrant inclusion. These criteria coincide with Ecology priorities as shown in legislation, such as the Children's Safe Product Act and initiatives such as the Puget Sound Partnership and Reducing Toxic Threats.

Table 3: QCAT Hazard Endpoints Compared with the GS®

| | QCAT | GS ® |
|--|----------------|-------------|
| Human Health: | | |
| Tier I | | |
| Carcinogenicity (C) | X | X |
| Mutagenicity & Genotoxicity (M) | X | X |
| Reproductive toxicity (R) | X | X |
| Developmental toxicity (incl. developmental neurotoxicity) (D) | X | X |
| Endocrine activity (E) | X | X |
| Tier II | | |
| Acute Mammalian Toxicity (AT) | X | X |
| Systemic & organ effects toxicity incl. Immunotoxicity (ST) | | X |
| Neurotoxicity (N) | | X |
| Sensitization: Skin (SnS) | | X |
| Sensitization: Respiratory (SnR) | | X |
| Irritation & Corrosivity: Skin (IrS) | | X |
| Irritation & Corrosivity: Eye (IrE) | | X |
| Ecological: | | |
| Acute Aquatic Toxicity (AA) | X | X |
| Chronic Aquatic Toxicity (CA) | | X |
| Other Ecotoxicity Studies (optional except for Benchmark 4) (Eo) | | X |
| Environmental: | | |
| Persistence (P) | X ⁵ | X |
| Bioaccumulation (B) | X | X |
| Physical: | | |
| Reactivity (R) | | X |
| Flammability (F) | | X |

The fewer endpoints clearly distinguish a QCAT from a GS® assessment. By including a wider range of hazard endpoints and requiring more detailed evaluation of the hazards involved, the GS® provides a greater degree of certainty concerning the hazards associated with each chemical.

There is a greater risk that chemicals of concern may be missed by the QCAT. However this increased risk is compensated for by the improved ability to implement the QCAT and reduced implementation costs. The QCAT also enables users to begin to understand the safer chemical alternatives process.

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⁵ Not needed as inorganics are assumed to be persistent. Clean Production Action is creating specialized rules for dealing with inorganic compounds. They will be incorporated into future QCAT updates.

The QCAT only looks at hazard-related criteria. Most alternatives assessments must consider other factors such as process engineering, performance, availability, existing usage, cost, energy balance, exposure, etc. Although the CHA and specifically QCAT are important components of an alternatives assessment, other factors should be considered before identifying a safer alternative.

C. QCAT Data Sources

Authoritative lists and summarized data sources leverage expert judgment and provide a reliable initial assessment of the hazards considered in evaluating a chemical. Data sources used to complete the QCAT for the nine hazard endpoints are selected in two steps. From authoritative sources, Step I leverages hazard lists and Step II uses specific databases and documents. Step 1 sources are further separated into Priority and Secondary Sources. Those sources listed as Priority are definitive determinations from authoritative sources that typically are not questions. Those sources listed as Secondary have some minor concerns. Therefore during an evaluation if the hazard data found differs between Primary and Secondary sources, emphasis should be given to the data from Primary sources. These steps (Table 4) are not unique to the QCAT but are informed by GS® and DfE data requirements.

Table 4: Two Steps of Data Collection for the QCAT

Data sources

Step I: Authoritative Sources:

Toxicity characteristics lists, databases, etc. generated by internationally recognized authoritative bodies or appropriate government agencies.

- Primary: determinations from sources deemed authoritive and not questioned.
- Secondary: sources with some minor concerns.

Data from Primary sources are given greater emphasis than data from Secondary sources.

Step II: Other Data Sources

Estimated Data: PBT Profiler, other non-sophisticated modeling tools.

Measured data: Specific information from publicly available risk assessments and databases, such as RTECS, ECOTOX, HSDB, etc.

Each step requires an increasing level of technical expertise. For example, Step I sources require little technical review or expertise and only a basic understanding of the hazard endpoints. The user simply determines whether a chemical appears on an authoritative list created by recognized experts in the field. If there is any conflict between the sources, greater emphasis is given to Primary sources. Step II requires sufficient technical expertise to evaluate data in the sources and reach a defensible conclusion about the applicability of the data. The QCAT includes instruction on how to find and interpret data from Step II sources. This reduces the need for technical expertise. A GS® evaluation (not included) requires experts knowledgeable and experienced in evaluating specific hazard endpoints. These advanced steps will not be used during a QCAT evaluation as this level of technical expertise is outside the QCAT's scope.

Chemicals identified in Step I sources do not need further evaluation. Presence in a Step I source is deemed authoritative and is sufficient for assigning a rank. Only chemicals that do not appear in Step I sources continue to Step II. For Step II sources, two or more individual sources should agree on the

rank. If only one Step II source is available, a rank can still be assigned; however, the QCAT report should document any limitations and indicate further review might be warranted.

In QCAT, Step II databases and documents are searched for applicable toxicity data pertinent to assigning a rank. No attempt is made to review the database or document sources as it is assumed they have already undergone peer review by experts. These databases and documents are assumed authoritative. For example, the National Institute of Medicine's Hazardous Substances Databank (HSDB) often contains information on toxicity values that are applicable to assigning a grade for a chemical. The HSDB sources are not reviewed, as a review would require more technical expertise than is expected for implementation of the QCAT.

Several organizations have compiled lists of chemicals of concern using these authoritative sources and these databases include many of the sources used in a Step I evaluation. Users may not need to compile a list of their own or need to decipher the information on all the individual sites but may defer to some of these compilations. Most of the files for a Step I review are available for free at the Chemical and Hazard Alternatives Toolbox, ChemHAT, created by a partnership between the IUE-CWA, the Industrial Division of the Communications Workers of America and the BlueGreen Alliance (BGA). ChemHAT does not use the GreenScreen ListTranslator® (LT®) benchmarks developed by Clean Production Action (CPA), the developer of the GS methodology. However, many of the authoritative lists used in the LT® can be found in ChemHAT, saving the assessor considerable time and effort by collecting many Step I data sources in one location.

Other sites are available that, for a fee, enable a quick evaluation of Step I resources. An automated version of the authoritative lists used in the GS[®], the GreenScreen ListTranslator[®] (LT[®]), was developed through a partnership between the CPA and the Health Building Network (HBN), an association of environmentalists interested in healthier building products.⁶

The LT[®] compares chemicals against data in authoritative lists for all 18 GS[®] hazard endpoints and identifies any for specific chemicals. Chemicals are separated into three categories:

- 1. LT-1: Chemicals that have specific hazard concerns.
- 2. LT-P1: Chemicals that may be an LT-1 but need further technical review.
- 3. LT-U: Chemicals with unknown ranking based on the sources used.

As the LT®, QCAT and GS® all use the same authoritative lists, any chemical identified as an LT-1 would automatically equate to a QCAT Grade F and GS® Benchmark 1. The user should document the specific hazard criteria and the authoritative body making the identification in the final QCAT report. The chemical is assigned a Grade F and no further evaluation is necessary.

The HBN developed Pharos, a database containing the hazard information found in Step I sources. Pharos creators define it as '...a partnership, pairing those who use building materials with those who study the

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⁶ Healthy Building Network

products' impacts on health and the environment.' Pharos is available only to those who pay a nominal yearly fee, currently \$20 per month. Other options are also available. An assessor who has access to the Pharos database can quickly identify any hazards from Step I authoritative sources.

In addition to Pharos, free sites are also available. The major limitation to the free sites, however, is that they often are not updated on a regular basis and may not contain up-to-date Step I sources. Recent additions or deletions from authoritative lists may not be included. The Chemical Hazard and Alternatives Toolbox (ChemHAT) is a free source that can help an assessor conduct a QCAT analysis. ChemHAT '...is a new internet database designed to offer up easy to use information that we can use to protect ourselves, our families and our co-workers against the harm that chemicals can cause. ChemHAT is based on the simple idea that when we know how a chemical can hurt us we can take protective action.' The advantage to ChemHAT is that a wide range of current information is freely available to all interested parties.

As part of its implementation of the Children's Safe Product Act, Ecology compiled chemicals from authoritative sources into one specific source called High Priority Chemicals or HPCs.⁸ The States of Maine⁹ and Minnesota¹⁰ generated similar lists based on the same sources, which are also publicly available. Several other lists exist, so a user may wish to review the different compilations and decide if any would assist in their evaluation process. The Interstate Chemicals Clearinghouse (IC2) has compiled these lists into a single source. A user can search the IC2 database and find out if a chemical was identified by a specific state and what hazard criteria caused it to be placed on the state list.¹¹

D. QCAT Data Gap and Grading Processes

The QCAT grading process is based on EPA's DfE methodology and subsequent changes reflected in the CPA GS[®] benchmarking method. The first step in the grading process is to assign a degree of concern using all data from Step I and II sources. The data are compared to the ranking criteria established (Appendix 8) and assigned one of five rankings ranging from very high (dark red), high (red), moderate (yellow), low (green) and very low (dark green). The color coding provides a visual representation of the level of concern associated with each hazard. The ranking results can be displayed visually (Table 5):

Table 5: Example of QCAT Reporting Table

| Hum | nan He | alth Gr | oup 1 | (HH1) | Human Health Group 2 (HH2) | | | | | Ec | ologic | al | Fa | ite | Phys | sical | | |
|-----|--------|---------|-------|-------|----------------------------|----|---|-----|-----|-----|--------|----|----|-----|------|-------|----|---|
| C | M | R | D | E | AT | ST | N | SnS | SnR | Irs | IrE | AA | CA | Ео | P | В | Ex | F |
| Н | M | L | vH | DG | M | | | | | | | Н | | | vL | vL | | |

⁷ Healthy Building Network Pharos database.

⁸Stone and Delistraty, Sources of toxicity and exposure information for identifying chemicals of high concern to children, Env. Imp. Assess. Review, 2009 or the Washington's CSPA Process Used to Generate Reporting List

⁹ Maine Chemicals of High Concern

¹⁰Minnesota Toxic Free Kids Act Chemicals of High Concern

¹¹IC2 State Priority Chemicals Resource

Each box is highlighted to show the level of concern. The same table is used to report both QCAT and $GS^{@}$ results. Boxes highlighted in grey and crossed out represent hazard criteria used in $GS^{@}$ but excluded from a QCAT assessment. This presentation represents the increased risk involved with a restricted analysis like QCAT compared with a more comprehensive $GS^{@}$ review.

Once the levels of concern are identified, the next step is to assign a grade. Ecology has created a grading tool, which will evaluate the levels of concern identified for specific chemicals and calculate the three grades, Initial, Data Gap and Final. The QCAT user should consider making use of this tool. However, it is also important to understand the fundamentals of the grading process incorporated into this tool. The following sections provide details on both the grading and data gap processes.

QCAT grading and data gap analyses are a simplification of the GS^{\otimes} benchmarking and data gap processes. Any future changes to the GS^{\otimes} data gap and benchmarking processes will be reflected in future QCAT upgrades. An initial grade is assigned using the following decision logic (<u>Table 6</u>):

Table 6: QCAT Process for Assigning an Initial Grade

| Grade A | 1. Low P + Low T (AA, AT and all HH1 endpoints) |
|----------------|---|
| | 1. Moderate P; or |
| Grade B | 2. Moderate B; or |
| Grade B | 3. Moderate AA; or |
| | 4. Moderate AT or one or more HH1 endpoints |
| | 1. Moderate P + Moderate B + Moderate T (AA, AT, or any HH1 endpoint); or |
| | 2. High P + High B; or |
| Grade C | 3. High P + Moderate T (AA, AT, or any HH1 endpoint); or |
| | 4. High B + Moderate T (AA, AT, or any HH1 endpoint); or |
| | 5. Very High T (AA or AT). |
| | 1. PBT = High P + High B + [Very High T (AA or AT) or High T (HH1)]; or |
| | 2. vPvB = very High P + very High B; or |
| Grade F | 3. vPT = very High P + [very High T (AA or AT) or High T (HH1)]; or |
| | 4. vBT = very High B + [very High T (AA or AT) or High T (HH1)]; or |
| | 5. CMR = High T (HH1). |

| | | | Legend | | |
|-----|---|---|--------|---|--|
| AA | = | Acute Aquatic Toxicity | M | = | Mutagenicity/Genotoxicity |
| AT | = | Acute Mammalian Toxicity | P | = | Persistence |
| В | = | Bioaccumulation | PBT | = | Persistent, Bioaccumulative, & Toxic |
| C | = | Carcinogenicity | R | = | Reproductive toxicity |
| D | = | Developmental Toxicity | T | = | Toxic |
| E | = | Endocrine Activity | vBT | = | very Bioaccumulative & Toxic |
| HH1 | = | Human Health Group 1 (C, M/G, R, D, EA) | vPT | = | very Persistent & Toxic |
| HH2 | = | Human Health Group 2 (AT) | vPvB | = | very Persistent & very Bioaccumulative |

The grading process begins by evaluating available data against the Grade F criteria. If none of the Grade F criteria are met, the ranking results are compared against the Grade C criteria. If no Grade C criteria are met, the process continues until a grade is determined.

Once an initial grade has been assigned, the chemical must be subjected to a data gap analysis. As with the grading process itself, the data gap analysis is similar to the process established for the GS[®]. The process reviews the data gaps found in the chemical ranking table for a specific chemical and, if necessary, reduces the grade's final grade based on the number and relative importance of the data gaps.

The following provides details on the QCAT data gap analysis process:

Grade F: Any chemical that qualifies for a Grade F will not undergo a data gap analysis. Grade F is the lowest possible grade to which any chemical can be assigned. Therefore, any data gaps would only reinforce the assignment of a Grade F and are unnecessary. If your chemical has attained a Grade F based on existing data, continue with the review of other alternatives.

Note: The QCAT user is cautioned in placing confidence in any grade assigned above Grade F. Because QCAT uses fewer criteria and less data, the risk of incorrectly assigning any chemical anything other than a grade F increases substantially. The QCAT user, however, may wish to proceed and use the other grades as a further prioritization tool to winnow down potential alternatives. Those chemicals that receive the best QCAT grade may be subjected to a more complete GS® analysis to increase confidence in the chemical's ability to function as a safer alternative.

Grade C: If a chemical has been assigned a Grade C, data gaps could potentially adversely affect this grading. Based on the data gaps, the following evaluations are made:

- 1. Are there data gaps for *three or more* Human Health endpoints?
- 2. Is there a data gap for *any of the following*: Persistence, Bioaccumulation, Acute Mammalian Toxicity, or Acute Aquatic Toxicity?
- 3. Are there data gaps for *two* Human Health endpoints, <u>and</u> are the gaps anything *other than* Endocrine Activity <u>and</u> *one of the following*: Carcinogenicity, Reproductive toxicity, or Developmental toxicity?

If the answer is 'yes' to <u>any</u> of the above questions, a **Final Grade** of \mathbf{F}_{dg} is assigned.

The 'dg' indicates the chemical is assigned a Final Grade F, based on serious data gaps. It also communicates that, although the chemical is provisionally a Grade F, its grade can be revisited if data becomes available to fill in the data gap.

Grade B: If a chemical has been assigned a Grade B, data gaps could potentially adversely affect this grading. Based on the data gaps, the following evaluations are made:

1. Are there data gaps for three or more Human Health endpoints?

- 2. Is there a data gap for any of the following: Persistence, Bioaccumulation, Acute Mammalian Toxicity or Acute Aquatic Toxicity?
- 3. Are there data gaps for two Human Health endpoints, and are the gaps anything other than Endocrine Activity and one of the following: Carcinogenicity, Reproductive toxicity, or Developmental toxicity?
- 4. Are there data gaps for any Human Health endpoints other than Endocrine activity?

If the answer is 'yes' to \underline{any} of Questions 1, 2 or 3, a **Final Grade** of F_{dg} is assigned. If the answer is 'yes' to Question 4, a **Final Grade** of C_{dg} is assigned.

The 'dg' indicates the chemical is assigned a Grade C, based on serious data gaps. This communicates to the manufacturer that, although initially a Grade B, the final grade was adjusted, based on the data gaps. The final grade can be revisited once data are available to fill in data gaps.

Grade A: If a chemical has been assigned a Grade A, data gaps could potentially adversely affect this grading. Based on data gaps, the following evaluations must be made:

- 1. Are there data gaps for three or more Human Health endpoints?
- 2. Is there a data gap for any of the following: Persistence, Bioaccumulation, Acute Mammalian Toxicity, or Acute Aquatic Toxicity?
- 3. Are there data gaps for two Human Health endpoints, and are the gaps anything other than Endocrine Activity and one of the following: Carcinogenicity, Reproductive toxicity, or Developmental toxicity?
- 4. Are there data gaps for any Human Health endpoints other than Endocrine Activity?
- 5. Is there a data gap for Endocrine Activity?

If the answer is 'yes' to <u>any</u> of Questions 1, 2 or 3, a **Final Grade** of **F**_{dg} is assigned. If the answer is 'yes' to Question 4, a **Final Grade** of **C**_{dg} is assigned. If the answer is 'yes' to Question 5, a **Final Grade** of **B**_{dg} is assigned.

The 'dg' indicates the chemical is assigned a Grade B, based on a data gap. This communicates to the manufacturer that, although its chemical is initially assigned a Grade A, the final grade must be adjusted, based on the importance of the data gaps. The final grade can be revisited once data are available to fill in data gaps.

As observed above, no chemical using the QCAT methodology can be assigned a Grade A if any data are missing. Just because a chemical has obtained a high grade using QCAT, a further review should be completed using a full GS® analysis to be sure any of the missing criteria do not adversely affect its grade.

E. QCAT Grading Tool

An electronic tool is available that determines the three QCAT grades, i.e. the Initial Grade based on available data, the Data Gap Grade based on missing data and the Final Grade as defined by the QCAT methodology. It is important that QCAT assessors understand the grading process, however, and it is recommended that new assessors become familiar with the methodology before using the tool. Once the assessor is familiar with the process, the QCAT Grading Tool provides a quick determination of the three grades for any chemical being assessed. The QCAT Hazard Summary Table and three grades can be copied from the tool and placed directly into the QCAT Summary Report for the chemical of concern.

F. Results from the QCAT Grading Processes

Once the evaluation is complete for all the chemicals undergoing the QCAT review, the potential risks associated with each chemical can be compared directly. Those chemicals assigned Grade F should be removed from the manufacturing process. Safer alternatives should be sought for chemicals with a Grade C, although they can be used while the search begins. Grade B chemicals still have some room for improvement but they are closer to being 'green.' Grade A chemicals are protective of human health and the environment, based on the QCAT review. A manufacturer may wish to subject these chemicals to a GS® analysis to make sure that no unidentified hazard concerns exist. However, compared to other chemicals, Grade A chemicals do not pose a substantial risk for the priority endpoints used in the QCAT analysis.

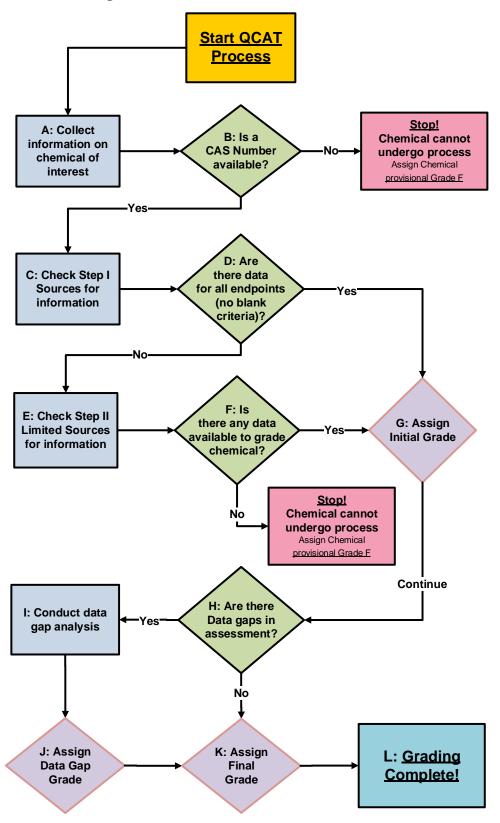
The QCAT decision logic is based on seven decision points that enable a user to complete the grading process. Before each decision point, data are collected to assist the user in making the subsequent decision. Each decision point will be assigned a number and is described below with the data collection requirements preceding the decision point.

The same method should be used to report results from the QCAT assessment as used for the $GS^{@}$ analysis. An example of a sample matrix is found in <u>Appendix 3</u>. Those hazard endpoints used in the $GS^{@}$ but omitted from QCAT are crosshatched. In this manner, it is clear the results from the QCAT lack analysis of certain hazard endpoints used in the $GS^{@}$ and that without this data, the uncertainty associated with the QCAT conclusions is greater.

4. QCAT Decision Logic

The QCAT decision logic and evaluation process is shown in Figure 1:

Figure 1: QCAT Decision Logic



5. Start QCAT Process

Lettered segments in this section correspond to the letters depicted in Figure 1.

A. Collect Information on Chemical of Interest

In order to begin the evaluation process, collect some basic information on each chemical, such as:

Required data:

• Chemical name

• CAS number

Optional data, if available:

- Octanol/water coefficient (typically displayed as log K_{ow})
- Potential degradation products
- Uses

B. Is a CAS Number Available?

A CAS number must be identified for each chemical to undergo the QCAT process. Without a CAS number, pertinent human health and environmental hazard data cannot be identified; therefore, a chemical without a CAS number automatically exits the process and is assigned a provisional Grade F (CAS). This assessment may change as manufacturers provide more information or EPA alters its interpretation of confidential business information.

C. Check Step I Data Sources for QCAT Hazard Endpoints

Appendix 1 identifies automated sources used in Step I for implementation of the QCAT. In Step I, the authoritative lists are evaluated to determine if any of the chemicals undergoing evaluation appear on these authoritative sources. As indicated previously, a pay site and several states and organizations have established lists of chemicals of concern that include many of the sources indicated in Step I. A user may wish to investigate these lists to see if any can be used in lieu of researching each individual source. See Appendix 1 for more details on two automated list translators, one free and one available at low cost. It is also possible to check the individual sources, which is time consuming and can lead to more interpretation errors. Where possible, it is highly recommended the assessor use one of the automated sources. Appendix 1 also provides information on how to obtain data from the individual authoritative sources.

The sources in Step I are primarily authoritative lists and the evaluation depends on whether or not a chemical appears on the list. The authoritative lists are divided into two categories, Priority and Secondary. Priority sources are lists from highly respected organizations that have reviewed all relevant data in detail. Individuals outside of the area of expertise are unlikely to disagree with the determinations provided by these sources. Secondary sources are lists from government and other organizations that may not have undergone as detailed a review. Therefore if determining which data to use to make a final determination, levels of concern identified by Priority sources have a higher level of confidence than levels of concern identified by Secondary sources. In essence, Priority sources trump Secondary.

Some lists also provide information on the relative level of concern for the chemical, based on available data and review by technical experts. For example, EPA's Integrated Risk Information System (IRIS) database using 1986 criteria identifies chemicals as known, probable, and possible carcinogens. Include these details in the assessment results, as they will assist in the grading process.

Four simple databases have also been included in Step I sources. Information is provided at the end of Appendix 1 on how a user may access data from these databases and what data should be recorded for the grading process. At this point, all available information from the authoritative sources will be entered into the chemical matrix for each chemical. To assist in review of the Step I sources, a checklist is provided in Appendix 10. The checklist identifies in green, the specific endpoints for which data may be found in each authoritative source. If no information is provided in the automated list translators, the assessor can identify by checking the specific box that no data was available from the specific source for the chemical under review.

D. Are There Data for all Hazard Endpoints?

Once a table has been filled in with appropriate data from Step I sources (see <u>Table 5</u> for an example), assessors determine if data have been found for all QCAT hazard endpoints. Hazard endpoints identified in Step I data Primary sources will not be evaluated further unless the only data available is from Step I Secondary sources. In this instance, the assessor may decide to review additional data sources to increase the confidence in the final determination. Presence in any Step I Priority source is deemed authoritative.

Only those chemicals that do not appear in Step I Priority sources should be subjected to further Step II review. If there is sufficient information to assign a final grade, the process jumps to grading (Step G in Figure 1).

E. Check Step II Data Sources for QCAT Hazard Endpoints

If any QCAT hazard endpoints remain blank after reviewing the data from Step I, research further for additional information using Step II data sources. Additional Step II data sources are identified in Appendix 2. The user should **look only for data to fill in any remaining gaps**. For example, if information was found in Step I Priority sources for carcinogenicity, there is no need to look for information in Step II sources. Step I Priority sources are deemed authoritative and can be used directly in the grading process without further review or additional information. Step I Secondary sources may also be used without further review unless the assessor decides to review Step II sources for additional data.

Several databases in Step II assist in assigning a hazard level to any remaining hazard endpoints. Appendix 2 offers guidance on how a user may access information in each database and what data should be recorded for the grading process.

The user should attempt to locate data from at least two Step II sources before ranking the chemical. If only one data source is found, the chemical can still be ranked using the information; however, the QCAT report should indicate that further review might be warranted based on the limited information available.

If after checking all Step I and II data sources, information has not been found for one or more of the QCAT hazard endpoints, enter a 'DG' for 'data gap' into the matrix for that hazard endpoint(s). 'DG' indicates that although all data sources were evaluated, no data were found to assign a rank for this chemical for this specific hazard endpoint.

F. Is There Data for any Hazard Endpoints That Can be Used to Grade the Chemical?

Once the table has been filled in with appropriate data from Steps I and II sources and any data gaps have been identified, determine if data have been found for one or more of the hazard endpoints. If data are found for one or more of the nine hazard endpoints, assess the data and begin the grading process identified in Step G (Figure 1).

If no data have been found using Step I and II sources, and only data gaps appear for all QCAT hazard endpoints, the chemical automatically exits the evaluation and is assigned a provisional grade 'F.' No further evaluation of this chemical occurs. Within the constraints of the QCAT system, this chemical is not a viable alternative to the toxic chemical being replaced. While data may exist for this chemical in sources not used by the QCAT and may identify this chemical as a viable alternative, this more detailed review is outside the scope of the QCAT.

G. Assign an Initial Grade to the Chemical

First, determine the level of concern for each hazard endpoint using the data collected from the Step I and II sources. The level of concern ranges from very low to very high and are color coded: very high (royal purple), high (red), moderate (yellow), low (light green) very low (blue). Such color-coding aligns with the GS[®] and DfE and assists in assigning an initial grade to the chemical.

Relative ranks are identified using the process explained in <u>Appendix 8</u>. The result is a matrix with ranks filled in for all endpoints (Table 7). The QCAT assessor should use this approach to display final results. As in the matrix used by DfE and GS^{\otimes} , it demonstrates the QCAT assessment is based on fewer hazard endpoints and therefore less exacting than a full DfE and GS^{\otimes} assessment.

Table 7: Example of Assigned Level of Concern for Each Hazard Endpoint

| | Hum | an He | alth (| Froup 1 | (HH1) | Hun | nan l | Hea | lth G | roup 2 | 2 (HI | H2) | Env | . Hea | lth | Fa | te | Phys | sical |
|---|-----|-------|--------|---------|-------|-----|-------|-----|-------|--------|-------|-------------|-----|-------|-----|----|----|------|-------|
| Ī | С | M | R | D | Е | AT | ST | N | SnS | SnR | Irs | IrE | AA | CA | Eo | P | В | Ex | F |
| | Н | M | Н | Н | DG | vH | | | | | | | Н | | | L | vL | | |

Once the levels of concern are assigned for each hazard endpoint with available data, an initial grade is assigned using the process described in <u>Table 6</u>. The result of this evaluation will assign an 'Initial Grade' as shown in Table 8.

Table 8: Example of an Initial Grade Assigned Based Upon the Levels of Concern Identified



Ignore data gaps at this point and assign a grade, based solely on what information is available. Further evaluation will assess any data gaps to determine what level of confidence can be assigned to augment the initial grade.

H. Are There Missing Data for any Hazard Endpoints?

In order to better coordinate data requirements with existing regulatory requirements, a process has been established in the GSTM to evaluate chemicals for data gaps in important hazard endpoints. This process has been incorporated into the QCAT method. If 'DG' is found for one or more of the hazard endpoints, a further assessment is required.

I. Conduct a Data Gap Analysis

Essentially, if a chemical undergoing the QCAT evaluation is missing data for one or more of the QCAT hazard endpoints, the impact these gaps may have on the initial grade assigned using available data is assessed.

The ideal scenario would be to find data to assign a hazard level for each hazard endpoint. In reality, there are chemicals for which no data are available for one or more hazard endpoints, and/or for which the chemical manufacturer is withholding data as confidential business information.

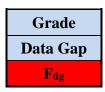
The GS[®] methodology Version 1.2 includes a data gap analysis. The intention of the data gap analysis and subsequent scoring is to promote and incentivize generation and disclosure of chemical hazard data. When data are missing and the hazard level for one or more hazard endpoints is unknown, use caution when benchmarking the chemical. More complete data sets are required to achieve each subsequent benchmark score (from red to green).

In essence, the data gap analysis attempts to quantify the confidence in the initial grade assigned to each chemical. If data exists for all the hazard endpoints, the confidence is high that the impacts to human health and the environment can be correctly assessed. If there are important data gaps, the confidence in the assessment decreases substantially. The QCAT is guided by the most current version of the GS[®] data gap analysis.

J. Assign a Data Gap Grade to the Chemical

The QCAT data gap process is very straightforward and is explained in more detail in the previous section 'Conduct a Data Gap Analysis'. If a chemical is assigned an initial grade F based on the data found, no data gap analysis is necessary, as data gaps will not adversely impact the assessment. If, however, a chemical is assigned any grade higher than an F, the data gap analysis will attempt to quantify the confidence of the assessment. Based on the data gap analysis, a 'Data Gap' grade is assigned (Table 9). The chemical has now been assigned two grades, one based on the data found (Initial Grade) and another based on data gap analysis (Data Gap Grade).

Table 9: Example of a Data Gap Grade Assigned Based Upon the Levels of Concern Identified



K. Assign a Final Grade

The assessor has identified two grades, the Initial Grade based on data found and the Data Gap Grade based on the number and importance of any data gaps. Based on these two grades, the chemical is assigned a Final Grade by selecting the lower of the two previous grades (Table 10) except for those chemicals assigned an Initial Grade of F. No data gap analysis is conducted for these chemicals and the Data Gap Grade is identified as Not Applicable (NA).

Table 10: Example of three Grades Assigned Based on the Levels of Concern Identified

| | Grades | | | | | | | | |
|---------|----------------------------|----------------------------|--|--|--|--|--|--|--|
| Initial | Data Gap | Final | | | | | | | |
| A | $\mathbf{F}_{\mathbf{dg}}$ | $\mathbf{F}_{\mathbf{dg}}$ | | | | | | | |

L. Grading Complete!

Congratulations! You have successfully completed the QCAT process. You can now summarize the grades assigned to all of the chemicals you have assessed using the QCAT. As part of the QCAT process, summarize the results of a QCAT evaluation for each chemical evaluated into a standardized format as shown in Appendix 6. The standardized format is based on a similar report used to report the results from a GS^{\otimes} evaluation. The details of the evaluation are documented and available for sharing with other interested parties. An example of a completed format for a QCAT evaluation is shown in Appendix 7.

It is important to understand how to interpret the grades. A chemical could receive a very high grade, based on what is known about it. However, if data on important priority endpoints are missing, there is less confidence that this grade actually reflects the potential impact the chemical may have on human health and the environment.

Table 11 demonstrates these principles with a real life example. Ecology evaluated several chlorinated solvents against four fluorinated compounds that were being sold as safer alternatives. The two compounds listed in Table 11 appear to have the lowest impact on human health and the environment. Although the fluorinated compound received a better initial grade (B versus C for the chlorinated compound), uncertainty about the Grade B is greater because data for an important hazard endpoint (acute aquatic toxicity) is missing. The fluorinated compound's initial grade has greater uncertainty, as this chemical has unknown toxicity to the environment and the grade is reduced to $F_{\rm dg}$ to represent this greater uncertainty.

Although the chlorinated species received a lower grade 'C,' data for all of the six priority endpoints are present for the chlorinated species. Only endocrine activity and carcinogenicity data are missing. The chlorinated species have data for mutagenicity/genotoxicity, which can give an indication of whether these chemicals may be carcinogenic. Thus, the lack of a carcinogenicity study for the chlorinated species is not considered fatal to the evaluation and the grade after considering data gaps remains at 'C.'

Table 11: Example of Two Halogenated Solvents

Chlorinated Fluorinated

| Н | Human Health - Grp 1 | | | | | Human Health - Group 2 | | | | | | | Ecological | | | Fate | | Physical | |
|----|----------------------|---|---|---|----|------------------------|----|---|-----|-----|-----|-----|------------|----|----|------|----|----------|---|
| (| 7) | M | R | D | E | AT | ST | N | SnS | SnR | IrS | IrE | AA | CA | Eo | P | В | Ex | F |
| De | G | L | L | L | DG | M | | | | | | | M | | | vH | vL | | |
| L | , | L | L | L | DG | L | | | | | | | DG | | | | vL | | |

| | Grades | | | | | | | |
|-------------|---------|----------------------------|----------------------------|--|--|--|--|--|
| | Initial | Data Gap | Final | | | | | |
| Chlorinated | C | C | C | | | | | |
| Fluorinated | В | $\mathbf{F}_{\mathbf{dg}}$ | $\mathbf{F}_{\mathbf{dg}}$ | | | | | |

The QCAT does allow incremental improvements, which may be necessary until data for all hazard endpoints become available. For example, you have two chemicals that have obtained Grades B and C respectively, based on available data. However, after the data gap analysis, the chlorinated compound received a Grade C and the fluorinated compound a Grade F_{dg} due to data gaps.

If a decision was made between these two chemicals based on the initial Grade, the fluorinated compound would be considered a safer choice, i.e., select the chemical with a B grade over the one with a Grade C. However, upon further data gaps review, very important information is missing for the fluorinated compound and selection of the fluorinated alternative is actually risky due to the lack of important data. The user may wish to contract with a toxicological service to conduct a more detailed GS® assessment.

Without additional data, a clear choice cannot be made between the two options. The final user would decide which chemical to use or, perhaps more appropriately, explore whether other alternatives are more well-defined and have less of an impact on human health and the environment. Until data on all the QCAT endpoints are available, however, the risk of making a choice about a chemical with unknown hazards cannot be evaluated. Thus, data gaps are important in the evaluation process.

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Appendix 1: Step I Data Sources

Individual Databases:

As mentioned previously, internet resources are available that accumulate information from many of the Step I lists into a single site. These sites may make a Step I evaluation easier for QCAT users. Detailed information on how to access each of these sites and obtain data that can be used in a QCAT evaluation can be found later in this appendix. The two sites of potential interest to QCAT users are:

- 1. The IUE-CWA, the Industrial Division of the Communications Workers of America's and the BlueGreen Alliance (BGA)'s Chemical and Hazard Alternatives Toolbox, ChemHAT.
- 2. Healthy Building Network's <u>Pharos Database</u>'s Chemical and Material Library.

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using

the most current version.

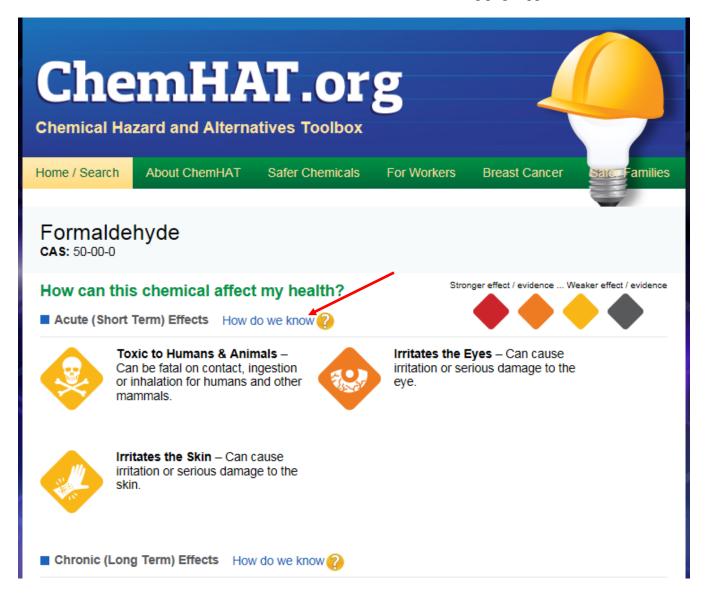
Users should check when the information on these websites was last updated. Any site that is several years out-of-date should be used with caution. However, if a chemical was identified as a problem in one of the lists included in these sites, the chemical should be avoided and removed as a potential safer alternative.

ChemHAT (Chemical and Hazard Alternatives Toolbox):

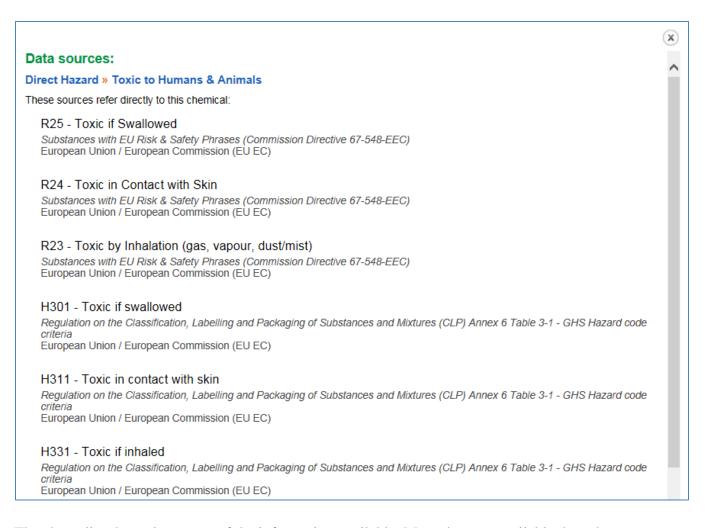
ChemHAT is a free site created by the Industrial Division of the Communications Workers of America and the BlueGreen Alliance (BGA). ChemHAT provides recommendations and identifies concerns for specific chemicals within its database. However, the data used for these recommendations are most of the same lists used in a Step I QCAT assessment. As ChemHAT is freely available to all users, it is a great source of authoritative lists and saves the assessor considerable time by providing most of the lists in one locate. Assessors can access ChemHAT through its main page:



The assessor can enter either the chemical name or the CAS number for the chemical of interest. The formaldehyde CAS number, 50-00-0, is used to demonstrate the availability of information within ChemHAT. Once the assessor clicks on the 'Find' button, the following page appears:



ChemHAT displays information on how the chemical can affect health. In the above screen capture, acute and chronic concerns are identified. If the assessor clicks on the blue highlighted information 'How do we know' in the Acute (Short Term) Effects category (red arrow above), the following information appears:



The above list shows just some of the information available. More data are available than shown.

The sources identified above are Step I data sources and the data would be used to help identify the level of acute toxicity concerns associated with formaldehyde. This window can be closed by clicking on the 'X' in the upper right corner.

Similar data are available for chronic concerns associated with formaldehyde:

Data sources:

Direct Hazard » Cancer

These sources refer directly to this chemical:

R40 - Limited Evidence of Carcinogenic Effects

Substances with EU Risk & Safety Phrases (Commission Directive 67-548-EEC) European Union / European Commission (EU EC)

H351 - Suspected of causing cancer

Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Annex 6 Table 3-1 - GHS Hazard code criteria European Union / European Commission (EU EC)

Carcinogen Group 4 - Non-genotoxic carcinogen with low risk under MAK/BAT levels

List of Substances with MAK & BAT Values & Categories MAK Commission of Germany (Deutsche Forschungsgemeinschaft)

(1986) Group B1 - Probable human Carcinogen

Integrated Risk Information System Database (IRIS) US Environmental Protection Agency (US EPA)

Group 1 - Agent is Carcinogenic to humans

Monographs On the Evaluation of Carcinogenic Risks to Humans International Agency for Research on Cancer, World Health Organization (IARC)

Carcinogen

Chemicals Known to the State to Cause Cancer or Reproductive Toxicity - California Proposition 65 - Safe Drinking Water and Toxic Enforcement Act Of

California Environmental Protection Agency (CA EPA)

Known to be a human Carcinogen

Report on Carcinogens

US Department of Health & Human Services - National Institutes of Health (US NIH)

This data indicates formaldehyde is a carcinogen and the specific data results can be used in QCAT to identify a level of concern. By using this single source, however, assessors can obtain carcinogenicity data from multiple authoritative sources without the need to visit each source individually.

If the assessor scrolls further down the initial results page for formaldehyde, the following information appears and data are available on formaldehyde's aquatic toxicity (red arrow):

How does this chemical impact the environment? How do we know?





Immediate Harm to Aquatic Ecosystems – A single exposure may result in severe biological harm or death to fish or other aquatic organisms.

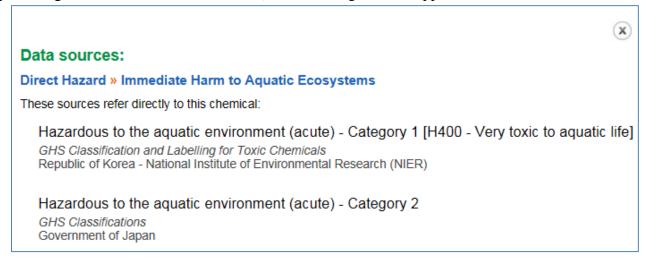


Bioaccumulative – Accumulates in organisms, concentrating as it moves up the food chain.



Persistent – Does not break down readily from natural processes.

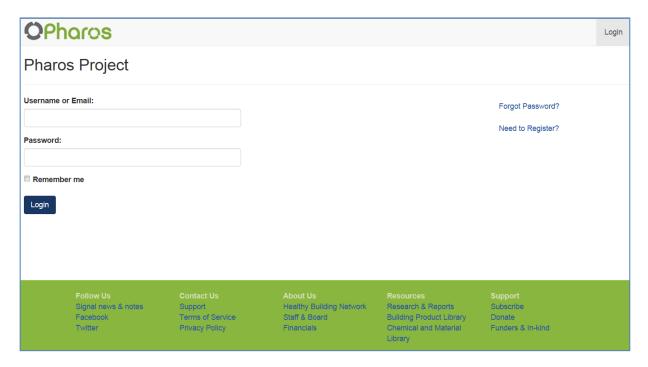
By clicking on the 'How do we know' link, the following window appears:



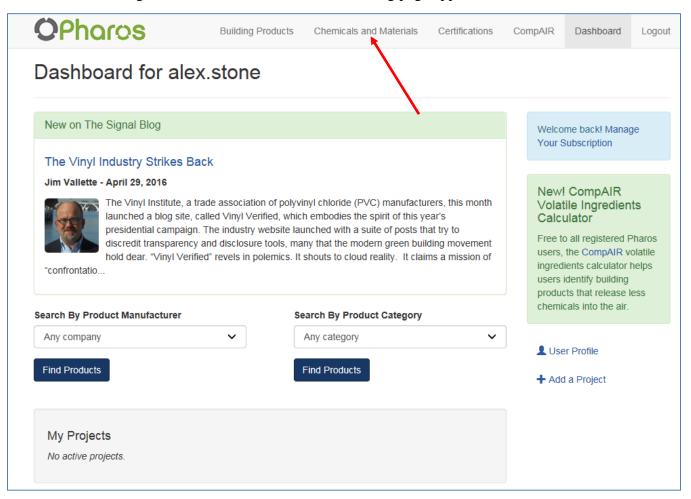
Information from ChemHAT can be used to assign a level of concern. For example, based upon the information displayed for formaldehyde, it would receive a Grade F based upon the high degree of carcinogenicity. Assessors should make the effort, however, to fill in as many of the hazard endpoints as possible. Although ChemHAT contains most of the Step I authoritative sources, it may not contain all and some of the other, more complete sources listed below may also be reviewed.

Healthy Building Network's Pharos Database:

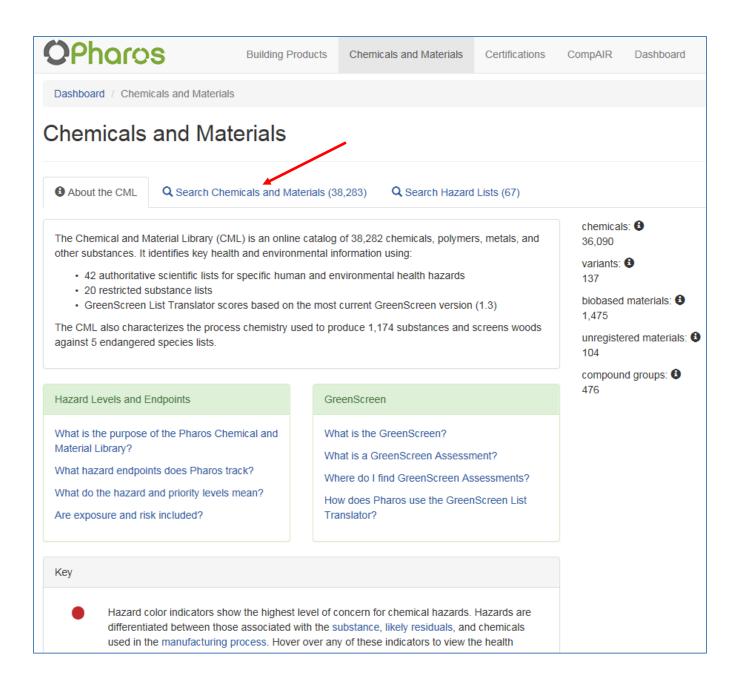
Pharos is a subscription site and may not be available to all users. Costs for access, however, are reasonable and access to the information in Pharos might justify the expense. Although Pharos was created primarily to improve the quality of building products, the data in its Chemical and Material Library is useful to QCAT users. Pharos also has the added benefit of being constantly reviewed and updated so the data are maintained and kept current. Users login to Pharos through its main page:



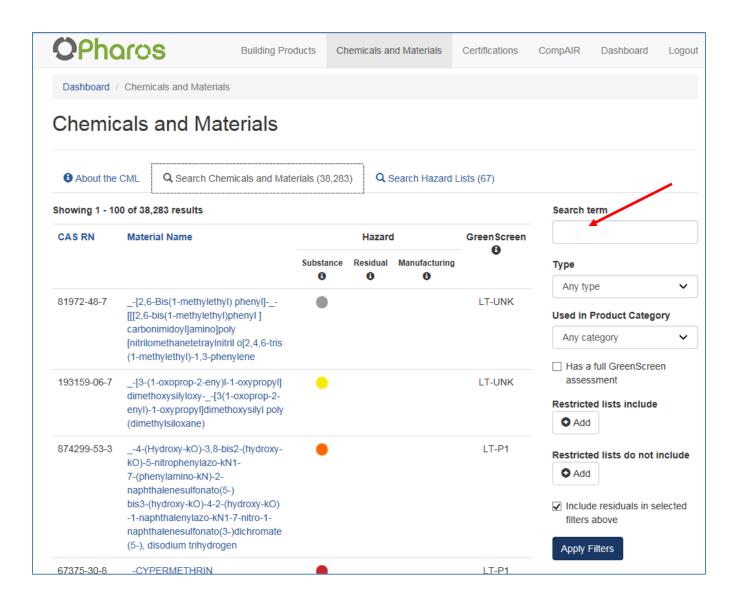
Once the assessor logs in and accesses the site, the following page appears:



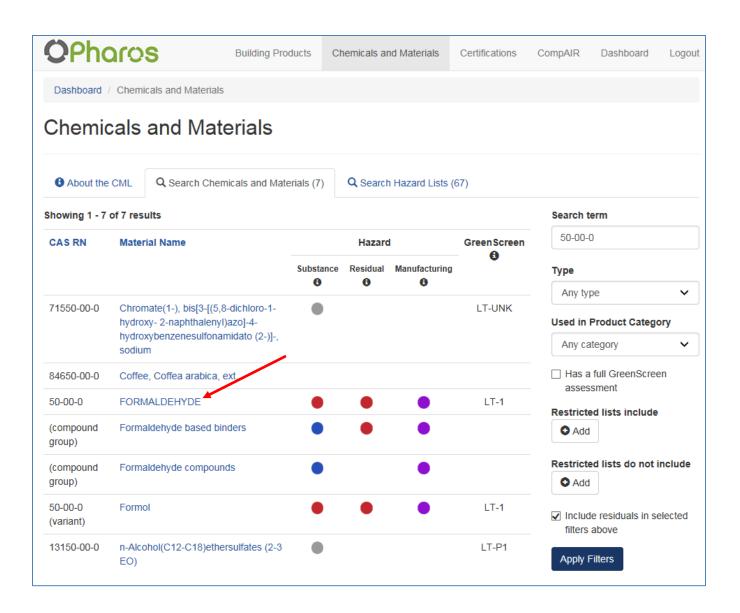
Each user has his or her own 'Dashboard', the contents of which might change as HBN posts news and other information for all Pharos users. Clicking on 'Chemicals and Materials' along the top (red arrow), takes you to the following page:



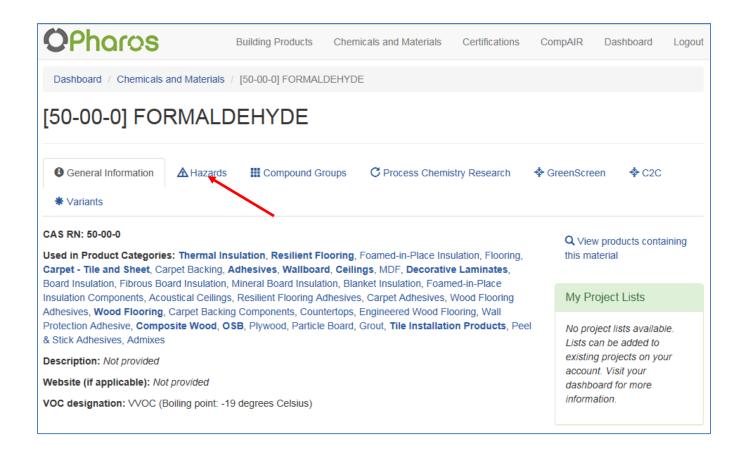
More information is found on the page. The goal, however, is to search for a specific chemical of interest. Clicking on the 'Search Chemicals and Materials' (red arrow) leads you to the following page:



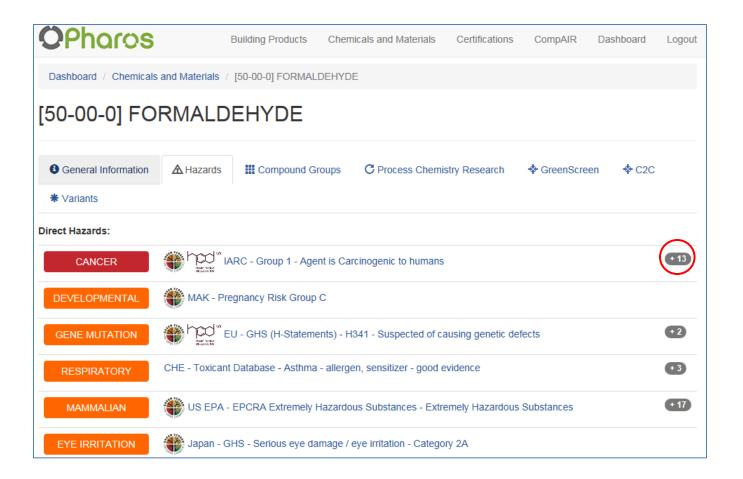
All chemicals in the library are available and the user must now narrow the focus to the chemical of interest. Using formaldehyde as an example again, type the CAS Number '50-00-0' in the box labeled 'Search term' (red arrow). The following information appears:



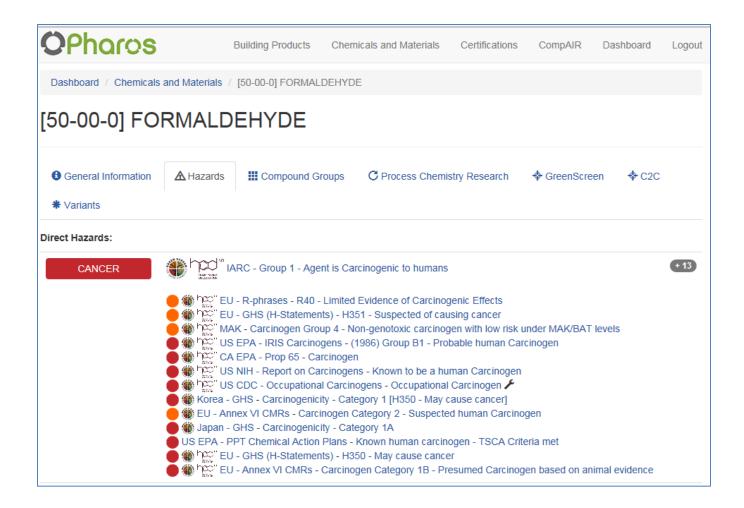
Pharos lists all entries containing '50-00-0.' Clicking on 'Formaldehyde' with the correct CAS (red arrow) causes the following to appear:



We are not quite there yet but close. Remember that Pharos was actually designed to help the building industry choose safer alternatives. The Hazard library is just one of the services Pharos provides. If, however, you click on the tab 'Hazards' above (red arrow), you'll get to the data you want:

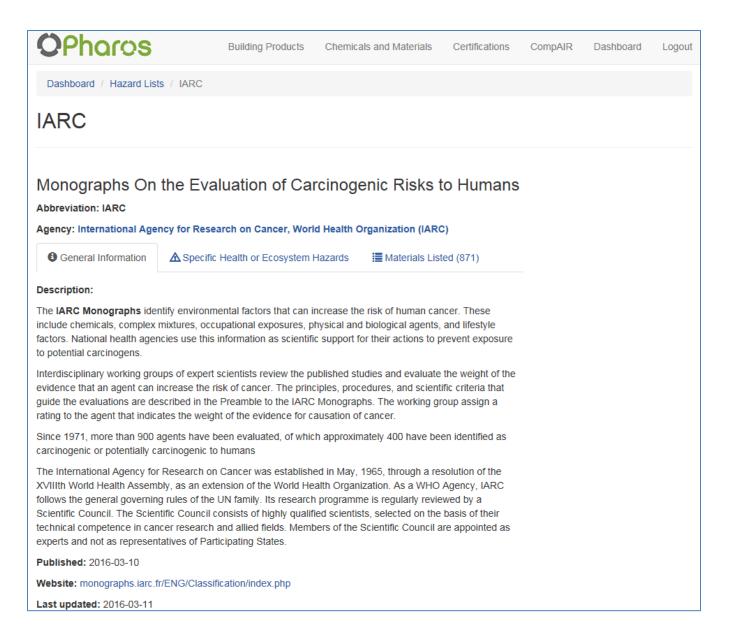


The above is just some of the information found in the database. Pharos is a certified GreenScreen ListTranslator[®] and the colors shown agree with the level of concern identified in GreenScreen[®] and used in QCAT. Therefore any hazard endpoint in red is likely to be a higher level of concern than those in orange. Pharos lists one source for each endpoint and identifies additional sources available. The '+13' after 'Cancer' (circled in red) indicates there are an additional 13 authoritative sources that reviewed and provided an opinion on cancer. This information is accessed by clicking on the '+13' and the following appears:

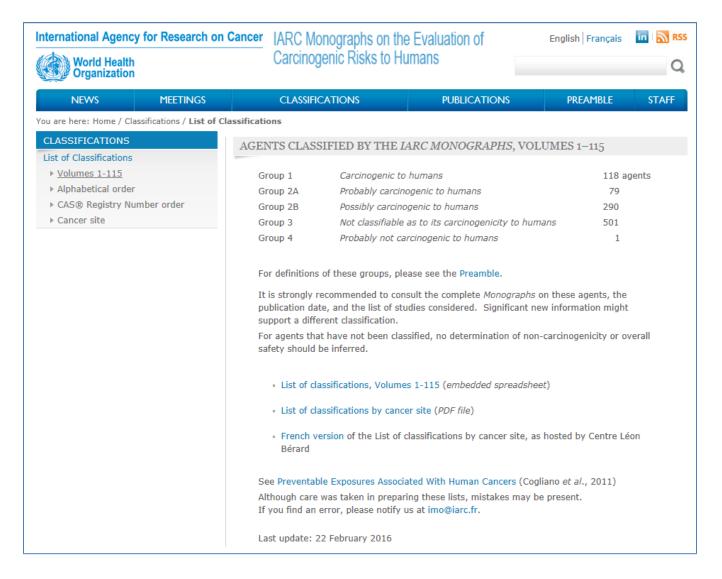


Pharos includes information on several hazard criteria. However, the only one pertinent to a Step I QCAT formaldehyde assessment is 'CANCER' as indicated by the red color. Note the colors used in Pharos align with the color-coding used in QCAT and GS[®]. Pharos indicates that formaldehyde is a 'Group 1: Agent is carcinogenic to humans' as identified by IARC. This indicates formaldehyde is an 'LT-1' for ListTranslator category 1, which is equivalent to a GS[®] Benchmark 1 or QCAT Grade F.

If you want more information on each source or are not sure what 'IARC' stands for, you may click on the entry, which takes you to the following:



Pharos indicates that IARC stands for the 'International Agency for Research on Cancer' by the World Health Organization as represented by their publications 'Monographs on the Evaluation of Carcinogenic Risks to Humans.' If interested, you may also go directly to the IARC site by clicking on the link next to 'Website:'. For example, clicking on this link takes you to the following:



Pharos does an excellent job providing information on each source and what the source's determination means. This information an be easily used by tools such as QCAT and GS to conduct a CHA.

All information available in Pharos on the cancer hazard endpoint is shown. Some information pertinent to a QCAT assessment includes:

- 1. Group 1: Carcinogenic to humans (IARC)
- 2. Known to be a human carcinogen (NTP RoC)
- 3. Group B1 using 1986 Guidelines (IRIS)
- 4. Carcinogenic (Prop 65)
- 5. Carcinogen (OSHA)
- 6. GHS Carcinogenicity Category 1, H350 May cause cancer (Korea NIER)
- 7. GHS Carcinogenicity Category 1A (Japan METI/MOE)
- 8. Known human carcinogen (US EPA)

This data can be used to identify the level of concern for carcinogenicity. According to the information in <u>Appendix 8</u>, this information causes cancer and needs to be assigned a level of 'H.' The QCAT user should note this information in the assessment for formaldehyde and indicate where the information was obtained, i.e., the Pharos database accessed on a specific date.

Note that Pharos includes data from sources used in the GS^{\circledast} but not in QCAT. This information is meaningful to its target audience, i.e., suppliers of building materials. Although it is tempting to include this information in a QCAT assessment, it is beyond the QCAT's scope and should be reserved for a GS^{\circledast} assessment.

Appendix 2: Step II Data Sources

For the purposes of the QCAT, the Step II sources identified in the Checklist (Appendix 10) will be searched for specific information, which can be used to grade chemicals undergoing the assessment process. Although considerable information is available from all of these sources, only specific information will be selected for review in support of the objectives of the QCAT to limit the level of technical expertise necessary. Information used from each database will be described in detail at the end of this appendix.

Information on how to access information within the various sites will be presented later in this appendix after the list of data sources. Step II data sources include:

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

1. ISSCAN: InstitutoSuperiore di Sanita, 'Chemical Toxicity.'

ISSCAN evaluates chemicals based upon structural relationships and experimental data and ranks them for level of concern for carcinogenicity and mutagenicity. These rankings can translate into an equivalent level of concern within QCAT:

Carcinogenic ratings:

- a. Ranking = 3: Carcinogenic
- b. Ranking = 2: Undetermined or equivocal
- c. Ranking = 1: Non-carcinogenetic

Mutagenicity in Salmonella typhimurium (Ames test) rankings (SAL):

- a. Ranking = 3: Mutagenic
- b. Ranking = 2: Undetermined or equivocal
- c. Ranking = 1: Non-mutagenic
- 2. European Chemicals Agency, Classification and Labeling Inventory (C&L Inventory).

The European Chemicals Agency (ECHA) as part of its implementation of the REACH legislation has made all data submitted by manufacturers available. This data has not undergone review and

there are some concerns about its accuracy. However, it provides a valuable resource for chemical hazard assessments like QCAT and can be used until better data is available.

- 3. <u>European Union Risk Assessments</u> (EU Risk Assessments)

 The European Union conducted in the past an extensive program where risk assessments were conducted on specific chemicals of concern. These risk assessments may provide valuable information for a chemical hazard assessment tool like QCAT if one is available.
- 4. <u>National Institute of Occupational Safety and Health</u> (NIOSH), <u>Registry of Toxic Effects of Chemical Substances</u> (RTECS). Paid subscription. RTECS is provided by several organizations for a fee. The examples shown here are for demonstration only and are not to be taken as an endorsement of any particular RTECS provider.

RTECS is a toxicological database that contains peer-reviewed information from international journals, textbooks, technical reports, scientific proceedings, etc. RTECS reports the results of this review. Often, RTECS will not provide specific numerical values for evaluation but evidence on whether or not the chemical of concern demonstrates specific characteristics. RTECS does provide specific values for some endpoints. For example, RTECS often includes LD50 values that can be used to determine a level of concern for Acute Mammalian Toxicity using the Technical Criteria in Appendix 8.

The assessor should determine from this review whether RTECS provides evidence of carcinogenicity and to what degree, i.e., strong, moderate, or low. More information is provided in the following screen-capture section.

5. National Library of Medicine (NLM), Hazardous Substances Databank (HSDB). HSDB may contain information found in Step I sources. However, it may also report data beyond Step I sources. The assessor should select the 'full record' option and then search on portions of the term 'carcinogenicity.' More information on how to search the HSDB for this additional data are in the following screen-capture section.

6. The United Nation's Screening Information Datasets (SIDS), if available.

SIDS may report the results of studies and other information relevant to most of the hazard endpoints used in QCAT. Typically, the results are summarized and this information can be reviewed to determine whether evidence of concern does or does not exist for the chemical of concern. The assessor reviews this information to determine the level of concern. More information is available in the following screen-capture section.

7. <u>U.S. Department of Labor, Occupational Safety & Health Administration</u> (OSHA) <u>Occupational</u> Chemical Database.

OSHA compiles data from several sources for specific chemicals of concern including physical properties, emergency response information, NIOSH Pocket Guide, etc. If assessed, this data may be used to assign a level of concern for several endpoints used in QCAT.

8. <u>Danish Ministry of the Environment's Environmental Protection Agency</u> (Danish EPA) (Q)SAR Assessment of Chemical Properties of Substances.

The Danish EPA has created a database that contains predictions on the potential toxicity of approximately 166,000 chemicals. The database predicts toxicity for mutagenicity, carcinogenicity, reproductive toxicity, acute aquatic toxicity and acute mammalian toxicity, all of which are used in QCAT.

For the purposes of the QCAT, the full (Q)SAR database will not be used but a subset of more than 30,000 substances for which GHS classifications have been estimated. This information can be found in the Danish <u>Advisory List for Self-classification</u>. These GHS results are directly comparable to the GHS criteria included in QCAT's <u>Appendix 8</u>.

9. <u>U.S. Environmental Protection Agency (EPA), Ecological Toxicity</u> (ECOTOX) <u>database</u>.

EPA has collected data on aquatic toxicity and published the results in ECOTOX. Unlike the HSDB and other similar databases, EPA does not conduct a technical review of the studies but solely publishes the results. For this reason, should other sources that have been reviewed conflict with ECOTOX results, the reviewed studies should be given preference. In the absence of data, ECOTOX provides an excellent resource on the latest aquatic toxicity studies. ECOTOX results are typically reported in values such as LC₅₀, which can be compared against the Technical Criteria in Appendix 8 identifying a level of concern to be used in QCAT. More information is provided in the following screen capture section on how to access data in ECOTOX.

10. <u>U.S. Environmental Protection Agency</u> (EPA), <u>PBT Profiler</u>.

The PBT Profiler is a computer model created by EPA as a screening tool to predict a chemical's potential to persist in the environment. Persistence results are reported in half-lives for various media such as water, air, soil, and sediment. Bioaccumulation results are reported in Bioconcentration Factors (BCF). These half-lives and BCF values are compared against the Technical Criteria in Appendix 8 to determine a level of concern in QCAT for persistence and bioaccumulation.

The PBT Profiler reports results from computer modeling conducted by EPA. In the instance where other, non-modeling is available, less emphasis should be placed upon PBT Profiler results.

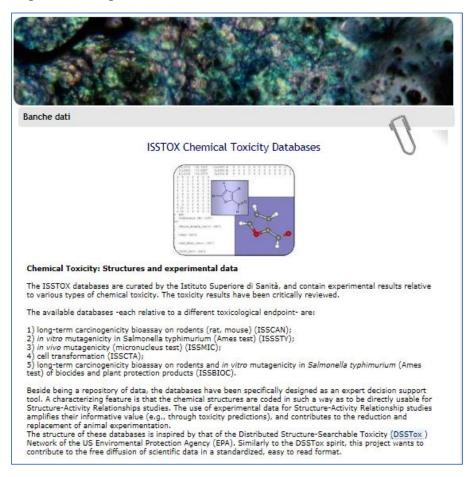
11. US EPA Characterization Criteria.

As part of EPA's New Chemical Program, hazard endpoints were parsed into various levels of concern to assist EPA to better identify chemicals, which may negatively impact human health or the environment. These criteria are used by EPA's Design for the Environment Program to assign a level of concern while conducting a chemical hazard assessment and were subsequently incorporated into the GreenScreen and QCAT methodologies.

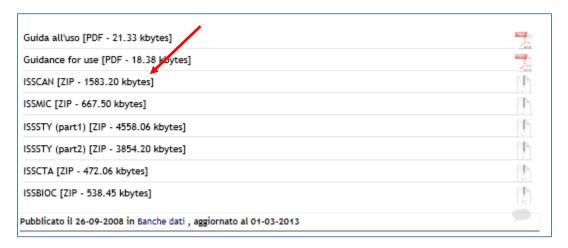
Examples of Data from Individual Databases used in Appendix 2

1. ISSCAN Chemical Carcinogens: Structures and Experimental Data

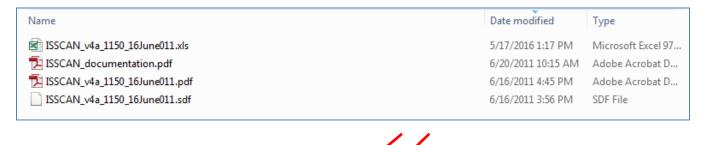
ISSCAN is an Italian database which contains information on carcinogen and mutagen potential based upon technical review of scientific studies and computer modeling input using Quality Structure Activity Relationship ((Q)SAR) processes.



The information is provided in an Excel spreadsheet (red arrow below) and information on both the carcinogenic and mutagenic potential is provided.



Once the ISSCAN file is downloaded and unzipped, the four files shown below are provided including background information on the process used to generate the data, abbreviations and an Excel spreadsheet with the results for each chemical.



Opening the Excel spreadsheet provides the following: 16 17 18 Substance ID Rat_Male_Cano FW ChemName Synonyms CAS Rat_Female_Cano Mouse_Male_Canc Mouse_Female_Ca 225.289 4-Dimethylaminoazobenzene 223.27 4-Acetylaminofluorene 202.251 Pyrene SolventYellow 2; Bi 4-AAF; 4-acetamid Benzo[def]phenant 60-11-1 28322-02-3 129-00-0 67-66-3 56-53-1 56-57-5 ND ND ND
 202.231
 Fylerie

 119.377
 Chloroform

 268.35
 Diethylstilbestrol

 190.156
 4-Nitroquinoline-N-Oxide
 Formyl trichloride; m 3,4-bis(p-hydroxyp 4-Nitroquinoline 1-c 2-Aminonaphthaler 1,1'-Biphenyl-4,4'-E 2-AAF; 2-Acetamic 2-Naphthylamine 184.237 Benzidine 2-Acetylaminofluorene 252,309 Benzo(a)pyrene 130,125 Hydrazine Sulphate 179,201 Hexamethylphosphoramide 3,4-benz[a]pyrene; Diamidogen sulfate; Hempa; Hexametap 50-32-8 680-31-9 ND N-Nitrosodiphenylamine Ethylenethiourea Diphenylnitrosamine 1,3-ethylene-2-thic

A great deal of information is provided. The QCAT assessor, however, is primarily interested in columns 13 and 14 (red arrows above) which summarize the results for carcinogenicity (Canc) and mutagenicity (SAL). The assessor can search the spreadsheet to determine if the CAS number for the chemical being evaluated is contained within this data. If so, it may be used to assign a level of concern.

3068-88-0

The Canc and SAL data are presented in ranges from 1 to 3 where:

3-Hydroxybutanoic

1,2-Methylenedioxy

1. 3 = carcinogenic or mutagenic

86.0892 beta-Butyrolactone 162.185 Safrole 73.0938 Dimothylformanide

- 2. 2 = undetermined or equivocal
- 3. 1 = non-carcinogenic or non-mutagenic

Some chemicals were not evaluated particularly for mutagenicity due to a lack of data and are identified as 'nd' for 'no data.'

For example, the ISSCAN provides the following information (additional detail excluded for the purposes of a QCAT review):

| ChemName | CAS | Canc | SAL^{12} | |
|----------------|---------|------|------------|--|
| Vinyl chloride | 75-01-4 | 3 | 3 | |

Therefore for QCAT, vinyl chloride would be identified as a known carcinogen and known mutagen.

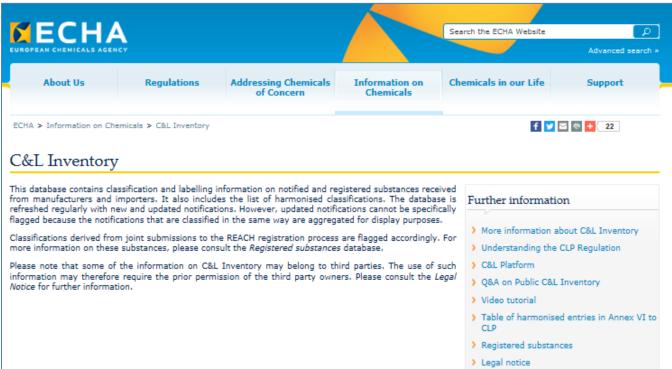
¹² SAL = Mutagenicity in *Salmonella typhimurium* (Ames Test)

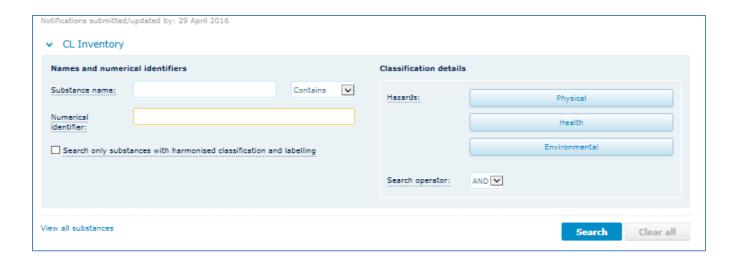
2. European Chemical Agency (ECHA) Classification and Labeling Inventory

The Classification and Labeling Database (C&L Database) is the result of the European Chemical Agency (ECHA) compiling all of the classification and labeling data submitted during chemical registration as required under REACH. ECHA made no attempt to review the submittals and there may be errors within the database. Since there is no incentive for a manufacturer to report a problem for a chemical if none exists, this database is potentially a good source for hazard data for chemicals that have been identified as containing some level of concern.

As the C&L Database has not been reviewed, there is less guarantee that chemicals in the database are correctly evaluated and there may be chemicals with hazard concerns that are not identified. QCAT users may wish to evaluate the information in this database for any data gaps remaining after evaluating other Step II sources. If a chemical is identified as a concern for any of the remaining hazard endpoints, the results can be used to define the degree of hazard involved. If there are any conflicts between this database and other Step II sources, the other sources may be given greater emphasis as this database has not been peer reviewed or audited.

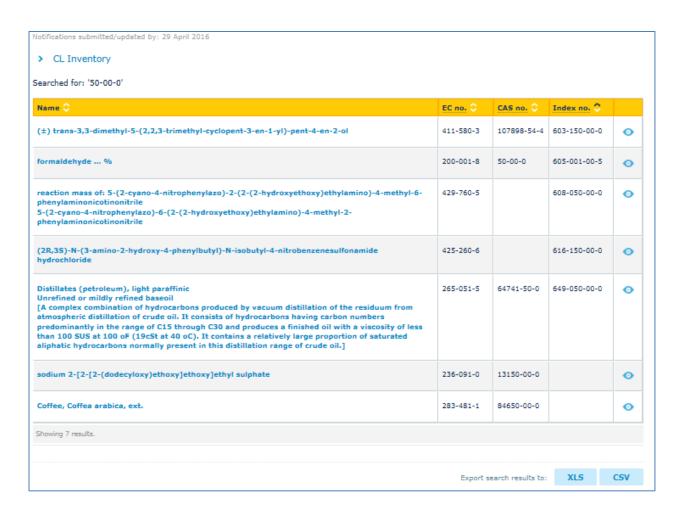
Access to the C&L database is straightforward. The opening page appears as:



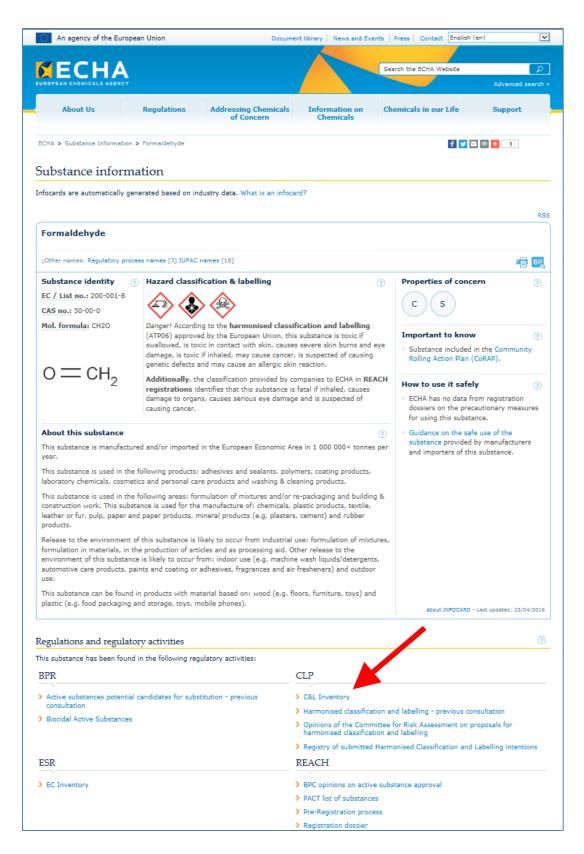


The QCAT user can search for information in several ways but the recommended method is to insert the CAS number in the line called 'Numerical Identifier.' The CAS No. for formaldehyde '50-00-0', for example, is typed into the first box 'Numerical Identifier' and the 'Search' button is pressed. The following page appears:





All of the entries that contain '50-00-0' are displayed. Clicking on the blue 'formaldehyde....%' leads to the following:



This page summarizes all the information currently available on formaldehyde in Europe. The information that is most useful to a QCAT assessor is 'C&L Inventory' (red arrow). Clicking on this link causes the following to appear:

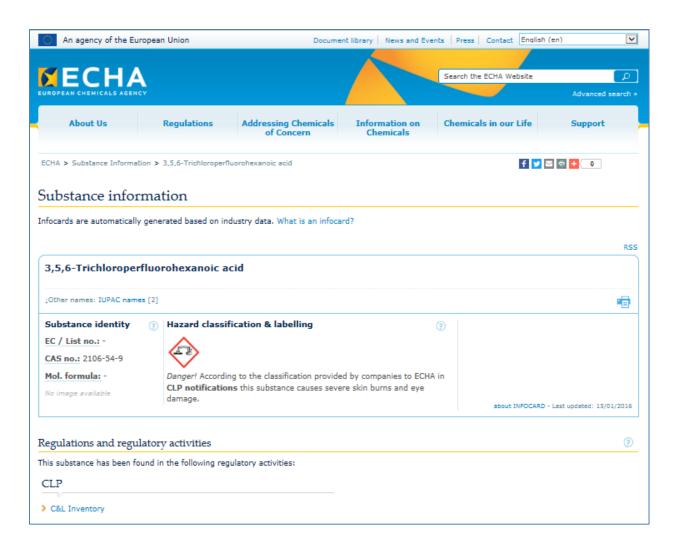


Much of the information on this page can be used to help assign a level of concern. The assessor can use the "hazard Class & Category Codes' (black box), the Hazard Statement Codes (red box), the Classification (green box) or the Risk Phrases (blue box), all of which can be found in Appendix 8. As these various codes are all related, the results should agree for all.

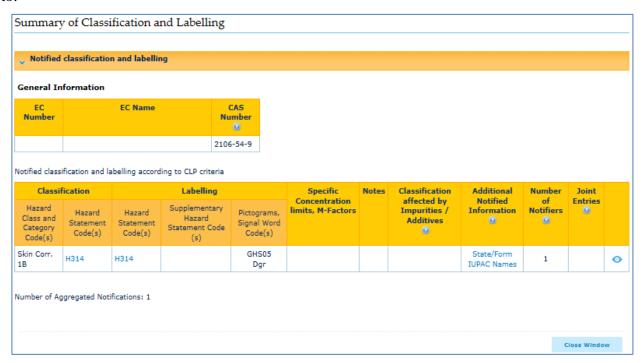
Not all chemicals have undergone such a detailed assessment. The assessor may have to be content with specific registration dossiers provided to the European Chemicals Agency as required by REACH. For example, the perfluorinated compound, perfluorohexanoic acid, was typed into the substance name. The search yielded the following:



The only compound to show was not the correct one but a trichloro related compound. In this instance, it would be appropriate to conduct another search using the correct CAS No. to see if the correct compound is shown. For the purposes of this example, however, the trichlorinated compound was selected and the following page appeared:



Less is known about this chemical compared with formaldehyde. Clicking on the 'C&L Inventory,' lead to:

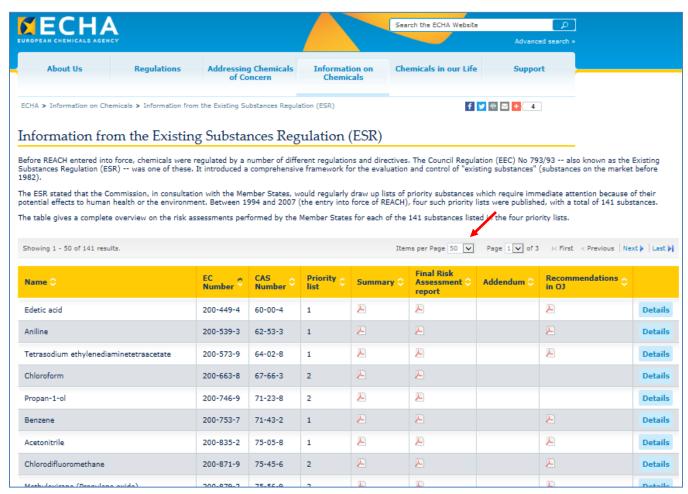


Skin Corrosivity, not used in QCAT, is the only concern identified for this chemical. One limitation on the REACH system is that it is not clear whether the chemical was subjected to a wide battery of tests and this was the only concern identified or if the compound was not tested for the other hazard endpoints. Legislation like REACH requires only limited testing for chemicals used in small amounts. More testing is required as the amounts created or imported into the European Union increase. Regardless this source provided no data that could be used in a QCAT.

If there are any questions about the source of the information, the column at the end provides more information on the chemical. This information is unlikely to be of interest to the standard QCAT user but is available if any questions arise.

3. European Union Risk Assessments (EU RAs)

Before REACH became the primary chemical legislation in the European Union, the European Commission maintained a list of 141 chemicals that have undergone or are undergoing the risk assessment process. Many of these reports can be found in the Classification and Labeling Database. ECHA has created a separate website where these EU RAs are made available. Using the link provided in the QCAT Checklist, the following page appears:



If a risk assessment has been completed for a chemical of interest, additional data reviewed during the process by experts in the various toxicity criteria and the conclusions reached may prove useful in filling any remaining data gaps. The QCAT assessor can display all 141 documents by changing the 'Items per Page' (red arrow above) from '50' shown to '200'. Once the page has refreshed, the user may search using the CAS number for the chemical under evaluation to determine if an EU RA has been done. Note: Striking the 'Ctrl' and 'F' keys simultaneously will bring up the 'Find' function into which you may enter the CAS number. If you use the 'Search the ECHA website' function shown in the figure above, you will be searching outside this area.

The EU uses a standardized format for all risk assessments, which makes access to information easier. The following is a page from the EU RA for trichloroethylene, which demonstrates the overall structure:

| 4 | HU | MAN I | HEALTI | I | 85 |
|---|-----|-------|---------|--|-----|
| | 4.1 | HUM | AN HE | ALTH (TOXICITY) | 85 |
| | | | | re assessment | |
| | | | | General discussion | 85 |
| | | | | Occupational exposure. | 85 |
| | | | | 4.1.1.2.1 Manufacture of trichloroethylene | |
| | | | | 4.1.1.2.2 Recycling trichloroethylene | |
| | | | | 4.1.1.2.3 Metal cleaning | 88 |
| | | | | 4.1.1.2.4 Adhesives | 91 |
| | | | | 4.1.1.2.5 Use as an intermediate | 92 |
| | | | | 4.1.1.2.6 Summary | 93 |
| | | | 4.1.1.3 | Consumer exposure | 95 |
| | | | | 4.1.1.3.1 Exposure to trichloroethylene from cloth cleaning | |
| | | | 4.1.1.4 | Humans exposed via the environment | |
| | | | 4.1.1.5 | Combined exposure | 97 |
| | | 4.1.2 | | assessment: hazard identification and dose (concentration) - response (effect) | |
| | | | | nent | 98 |
| | | | 4.1.2.1 | Toxicokinetics, metabolism and distribution | 98 |
| | | | | 4.1.2.1.1 Studies in animals | 98 |
| | | | | 4.1.2.1.2 Studies in humans | 112 |
| | | | | 4.1.2.1.3 Summary of toxicokinetics | 119 |
| | | | 4.1.2.2 | Acute toxicity | |
| | | | | 4.1.2.2.1 Studies in animals | |
| | | | | 4.1.2.2.2 Studies in humans | 129 |
| | | | | 4.1.2.2.3 Summary of acute toxicity | 139 |
| | | | 4.1.2.3 | Irritation | 140 |
| | | | | 4.1.2.3.1 Studies in animals | 140 |
| | | | | 4.1.2.3.2 Studies in humans | |
| | | | | 4.1.2.3.3 Summary of skin and eye irritation | 142 |
| | | | 4.1.2.4 | Corrosivity | 142 |
| | | | 4.1.2.5 | Sensitisation | 142 |
| | | | | 4.1.2.5.1 Studies in animals | 142 |
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| | | | | 4.1.2.5.3 Summary of sensitisation | 144 |
| | | | 4.1.2.6 | Repeated dose toxicity | 144 |
| | | | | 4.1.2.6.1 Studies in animals | 144 |
| | | | | 4.1.2.6.2 Studies in humans | 161 |
| | | | | 4.1.2.6.3 Summary of effects of repeated exposure | 188 |
| | | | 4.1.2.7 | Mutagenicity | 190 |
| | | | | 4.1.2.7.1 In vitro studies | 190 |
| | | | | 4.1.2.7.2 Drosophila | 195 |
| | | | | 4.1.2.7.3 In vivo tests | |
| | | | | 4.1.2.7.4 Human genotoxicity | |
| | | | | 4.1.2.7.5 Summary of genotoxicity | 202 |
| | | | 4.1.2.8 | Carcinogenicity | 203 |
| | | | | 4.1.2.8.1 Studies in animals | 203 |

The Risk Assessment Report (RAR) includes an evaluation of human health and environmental toxicity including many of the QCAT criteria including:

- Biodegradation
- Bioaccumulation
- Aquatic toxicity
- Acute mammalian toxicity

- Mutagenicity
- Carcinogenicity
- Reproductive toxicity

At the end of each toxicity criteria, the RAR typically either selects a value culled from the scientific data or reaches a conclusion, which may be useful to the QCAT process.

Chapter 4 deals with mammalian toxicity and includes a number of hazard criteria of interest. At the end of each section, the RAR summarizes what can be learned from the evaluation. Information in these summary sections may be useful when assigning a level of concern for specific hazard endpoints.

For example, Section 4.1.2.8 deals with carcinogenicity and subsection 4.1.2.8.3 'Summary of carcinogenicity studies' summarizes carcinogenicity conclusions that can be obtained from the previous discussions. Continuing with trichloroethylene as an example, the following information was copied from the end of the RAR section on carcinogenicity (page 231):

CHAPTER 4. HUMAN HEALTH

in support of category 1, underlined the evidence for kidney tumours in humans and the consistency with the S-(1,2-dichlorovinyl)-L-cysteine (DCVC) metabolic pathway and the observation of a different spectrum of somatic mutations in kidney tumours of trichloroethylene-exposed compared to unexposed patients.

A clear majority of the Specialised Experts recommended that classification of trichloroethylene as a category 2 carcinogen is warranted, based on evidence in one animal species, namely tumours in the rat kidney, supported by epidemiological data showing an association between exposure and kidney tumours and non-Hodgkin's lymphoma in humans. Some Specialised Experts stated that genotoxicity and metabolic/biochemical findings added to their concern. One expert maintained that category 1 was appropriate, one preferred category 3 but accepted the majority view.

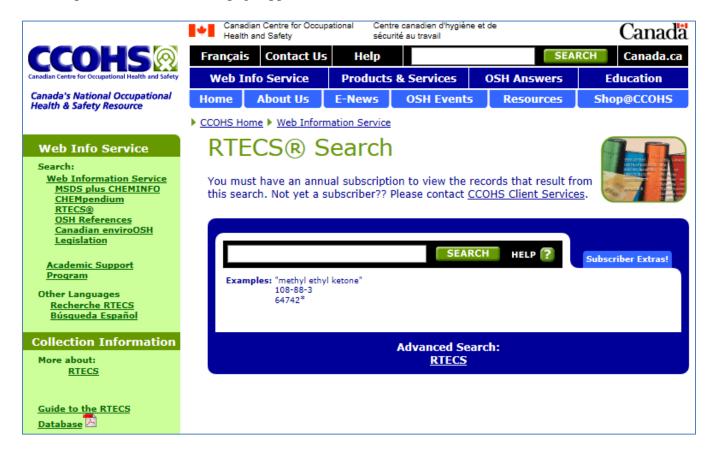
The summary information like 'A clear majority of the Specialised Experts recommended that classification of trichloroethylene as a category 2 carcinogen is warranted...' can be used by the assessor to identify a level of concern.

Unlike the sources in Step I, more searching is needed to determine the conclusions reached by the experts and reported in the RAR. In some instances, no distinct conclusion was reached. It is not expected that any of the details in the RAR would be used for the purposes of the QCAT if no conclusion was reached. Where such information is found, however, it may be useful in filling any data gaps which exist after a review using Step I sources. The QCAT review is limited to this level of review.

4. Registry of Toxic Effects of Chemical Substances (RTECS)

RTECS contains data on several toxicity endpoints, which may be of interest to a GS^{\otimes} evaluation. However, many endpoints require technical expertise to evaluate prior to including in a safer chemical alternatives assessment. For the purposes of the QCAT, the acute mammalian toxicity (LD₅₀ and LC₅₀ inhalation, dermal and oral data only) and tumorigenic/carcinogenicity data may prove useful.

RTECS is available from several sources and Ecology obtains access to the data through the Canadian Centre for Occupational Health and Safety (CCOHS). Other sources contain the same information. As an example, the CCOHS search page appears as follows:



Typing in the CAS No. for formaldehyde (50-00-0), leads to the following (Note: you may be required to enter a password at this point showing you have paid for access to the data):



Clicking on 'Formaldehyde' leads to the actual data:



This page indicates that data for acute toxicity, tumorigenic, reproductive and mutation data are available. Not all this data may be easily interpreted and may not be applicable to a QCAT. Clicking on 'Acute Toxicity Data' directs the assessor to this actual data. Much of the available data is not useful to the assessor as there are no criteria in Appendix 8 that can be used to interpret many of the endpoints

used. Appendix 8, however, does include information on how to assess LD₅₀, the dose that will kill 50% of the population. The following are examples of LD₅₀ data from RTECS:

Acute Mammalian Toxicity:

| ACUTE TOXICITY DATA | | | | | |
|--|-------------------|---------------------|--------------|---|---|
| Type of Test | Route of Exposure | Species Observed | Dose Data | Toxic Effects | Reference |
| LD50 - Lethal dose, 50 percent kill | Oral | Rodent - rat | 100 mg/kg | Details of toxic effects not reported other than lethal dose value | FCTOD7 Food and Chemical Toxicology. (Pergamon Press Inc., Maxwell House, Fairview Park, Elmsford, NY 10523) V.20- 1982- Volume(issue)/page/year: 26,447,1988 |
| LC50 - Lethal concentration, 50 percent kill | Inhalation | Rodent - rat | 203 mg/m3 | Peripheral Nerve and Sensation - spastic paralysis with or without sensory change Behavioral - convulsions or effect on seizure threshold Behavioral - excitement | GTPZAB GigienaTruda i Professional'nyeZabolevaniya. Labor Hygiene and Occupational Diseases. (V/O MezhdunarodnayaKniga, 113095 Moscow, USSR) V.1-36, 1957- 1992. For publisher information, see MTPEEI Volume(issue)/page/year: 18(2),55,1974 |

etc....

The RTECS acute toxicity dose data can be compared with the ranges in Appendix 8 and can be used to complete a QCAT evaluation for Acute Mammalian Toxicity.

Other data in RTECS may also be useful. For example, RTECS contains the following information for tumorigenic toxicity:

Tumorigenic/Carcinogenicity:

| TUMOR | TUMORIGENIC DATA | | | | | | |
|---|-------------------|---------------------|---------------------------------|--|--|--|--|
| Type of Test | Route of Exposure | Species Observed | Dose Data | Toxic Effects | Reference | | |
| TDLo - Lowest published toxic dose | Oral | Rodent - rat | 109 gm/kg/2Y (continuous) | Tumorigenic - carcinogenic by RTECS criteria ¹³ Gastrointestinal - tumors Blood - leukemia | TIHEEC Toxicology and Industrial Health. (Princeton Scientific Pub. Co., POB 2155, Princeton, NJ 08540) V.1- 1985- Volume(issue)/page/year: 5,699,1989 | | |

etc.....

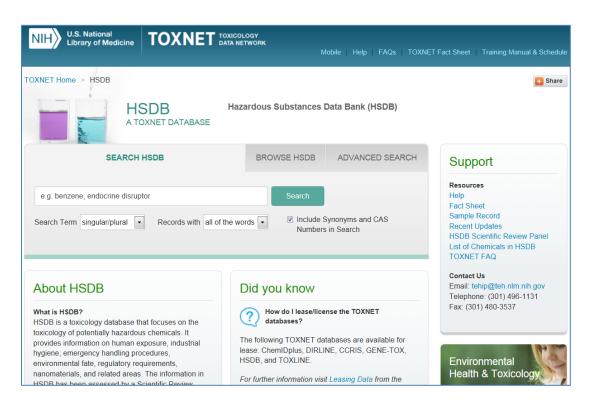
¹³ Emphasis added to show reviewer what information to use for making determination.

Although 'RTECS criteria' are not specifically called out in Appendix 8, it does meet the requirement of "Strong Evidence of Carcinogencity' and could be used to classify formaldehyde if other data sources were not already available. The determination of whether or not a chemical is determined as tumorigenic/carcinogenic using the data that meets the RTECS criteria may prove useful in completing a QCAT evaluation.

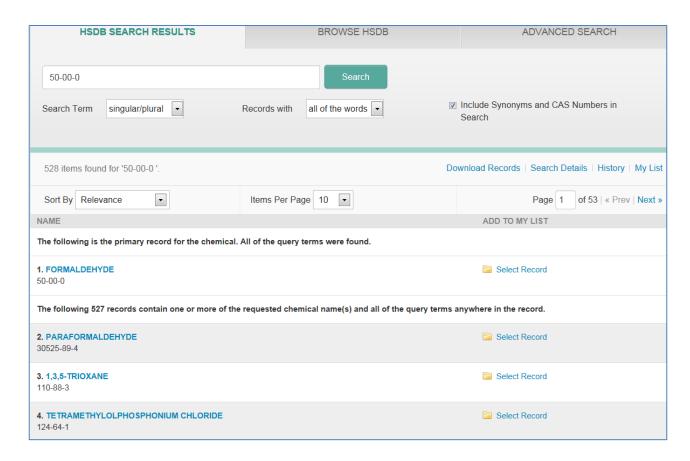
5. Hazardous Substances Databank (HSDB)

The HSDB contains considerable information on the toxicity of specific chemicals. This includes excerpts from specific sources and detailed information on the specific chemical impacts. HSDB also displays specific toxicity results, which have undergone technical review and conclusions on certain toxicity criteria, which will be of use in a QCAT evaluation. The three primary toxicity criteria of interest are acute mammalian toxicity, acute aquatic toxicity, and carcinogenicity. Information may be available on other toxicity criteria included in the QCAT; however, these data vary widely from chemical to chemical and should be used with caution.

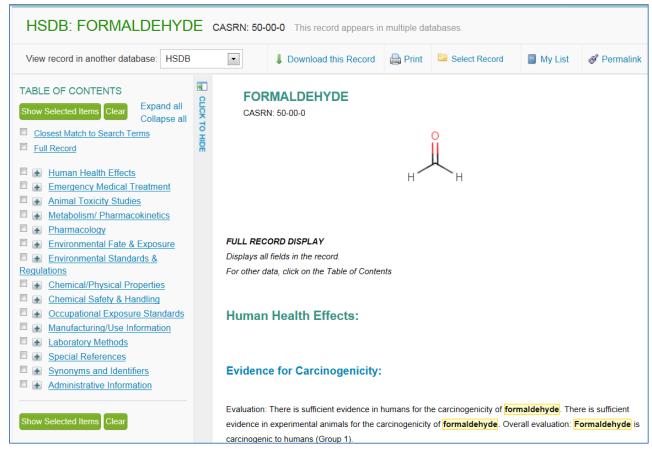
The following is HSDB's initial page:



As an example, the CAS number for formaldehyde (50-00-0) is entered into the 'Search HSDB' and the 'Search' button pressed.



Clicking on the blue 'Formaldehyde' takes the assessor directly to available data in the HSDB.



Clicking on the blue 'Human Health Effects' line on the left identifies human health data, a portion of which is shown below:

Evidence for Carcinogenicity:

Evaluation: There is sufficient evidence in humans for the carcinogenicity of formaldehyde. There is sufficient evidence in experimental animals for the carcinogenicity of formaldehyde. Overall evaluation: Formaldehyde is carcinogenic to humans (Group 1).

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Vol 88 Summary of Data Reported and Evaluation. (Last updated: September 7, 2004). Available from, as of June 22, 2006: http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf **PEER REVIEWED**

Cancer Classification: Group B1 Probable Human Carcinogen

[USEPA Office of Pesticide Programs, Health Effects Division, Science Information Management Branch: "Chemicals Evaluated for Carcinogenic Potential" (April 2006)] **QC REVIEWED**

CLASSIFICATION: B1; probable human carcinogen. BASIS FOR CLASSIFICATION: Based on limited evidence in humans, and sufficient evidence in animals. Human data include nine studies that show statistically significant associations between site-specific respiratory neoplasms and exposure to **formaldehyde** or **formaldehyde**-containing products. An increased incidence of nasal squamous cell carcinomas was observed in long-term inhalation studies in rats and in mice. The classification is supported by in vitro genotoxicity data and **formaldehyde**'s structural relationships to other carcinogenic aldehydes such as acetaldehyde. HUMAN CARCINOGENICITY DATA: Limited. ANIMAL CARCINOGENICITY DATA: Sufficient.

[U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS). Summary on Formaldehyde (50 -00-0). Available from, as of March 15, 2000: http://www.epa.gov/iris/ **PEER REVIEWED**

The Table of Contents on the left displays various pages of the report. Data in three specific pages will be discussed in the subsequent sections.

Acute Mammalian Toxicity: Under 'Animal Toxicity Studies', clicking on 'Non-Human Toxicity Values' provides acute mammalian toxicity values of interest for the QCAT evaluation:

Non-Human Toxicity Values:

LD50 Rat oral 100 mg/kg /SRP: percent solution not specified/

[Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 1814] **PEER REVIEWED**

LD50 Rat (albino) oral 2020 mg/kg /From table/ /SRP: percent solution not specified/

[Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 5:967] **PEER REVIEWED**

LD50 Rat oral 800 mg/kg /from table/

[Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 5:967] **PEER REVIEWED**

LC50 Rat inhalation 0.82 mg/L (1/2 hour)

[Tomlin, C.D.S. (ed.). The Pesticide Manual - World Compendium. 10th ed. Surrey, UK: The British Crop Protection Council, 1994., p. 525] **PEER REVIEWED**

Note: This screen capture presents only a portion of the data available and is representative of what the HSDB contains. Data may also be present in HSDB for routes of exposure not used in QCAT. The assessor should only use data for the routes identified in Appendix 8.

For the purposes of the QCAT, the LC₅₀ and LD₅₀ toxicity values provided are compared with the Technical Criteria in Appendix 8 to determine the level of concern.

Acute aquatic toxicity: Under 'Animal Toxicity Studies', clicking on 'Ecotoxicity values' provides acute aquatic toxicity values of interest for the QCAT evaluation:

Ecotoxicity Values:

LC50; Species: /Morone saxatilis/ (Striped bass) larvae; Conditions: static bioassay; Concentration: 10 mg/L for 48-96 hr [Environmental Canada: Tech Info for Problem Spills: Formaldehyde p.67 (1985)] **PEER REVIEWED**

LC50; Species: Oncorhynchus mykiss (Rainbow trout) weight 0.63 g; Conditions: static; Concentration: 118 ppm for 96 hr (95% confidence limit: 99.7-140 ppm) /37% Al formulated product/

[USEPA, Office of Pesticide Programs; Pesticide Ecotoxicity Database (2000) on Formaldehyde (50-00-0). Available from, as of May 30, 2006: http://cfpub.epa.gov/ecotox/quick_query.htm **PEER REVIEWED**

LC50; Species: Oncorhynchus mykiss (Rainbow trout) weight 0.81 g; Conditions: static; Concentration: >100 ppm for 96 hr /18.8% Al formulated product/

[USEPA, Office of Pesticide Programs; Pesticide Ecotoxicity Database (2000) on Formaldehyde (50-00-0). Available from, as of May 30, 2006: http://cfpub.epa.gov/ecotox/quick_query.htm **PEER REVIEWED**

Note: This screen capture presents only a portion of the data available and is representative of what the HSDB contains. In addition, data in HSDB may also be found in other sources such as EPA's ECOTOX database. Data in HSDB has undergone a peer review process and therefore can be assumed to be data conducted as required using best scientific practices.

For the purposes of ecotoxicity review, LC₅₀ fish data will be evaluated using the process established within Washington State's Dangerous Waste Regulations (WAC 173-303):

'Fish LC_{50} data must be derived from an exposure period greater than or equal to twenty-four hours. A hierarchy of species LC_{50} data should be used that includes (in decreasing order of preference) salmonids, fathead minnows, and other fish species.'

For other ecotoxicity data, the species with the most data are assumed to be indicative of the chemical's toxic effects. This information can be interpreted using the Technical Criteria for Acute Aquatic Toxicity in Appendix 8 and directly applied to the QCAT ranking criteria.

Carcinogenicity: Where available, the HSDB also provides an assessment of whether or not a chemical is a known or suspected carcinogen. Much of the information in this assessment is pulled from other sources used in the Step I analysis and may be duplicative. However, the HSDB does include other sources that may be useful in a Step II evaluation. For example, the carcinogenicity information on formaldehyde appears under 'Human Health Effects'. Clicking on 'Evidence for carcinogenicity' provides the following:

Evidence for Carcinogenicity:

There is sufficient evidence in humans for the carcinogenicity of formaldehyde. Formaldehyde causes cancer of the nasopharynx and leukaemia. Also, a positive association has been observed between exposure to formaldehyde and sinonasal cancer. There is sufficient evidence in experimental animals for the carcinogenicity of formaldehyde. The Working Group was not in full agreement on the evaluation of formaldehyde causing leukaemias in humans, with a small majority viewing the evidence as sufficient of carcinogenicity and the minority viewing the evidence as limited. Particularly relevant to the discussions regarding sufficient evidence was a recent study accepted for publication which, for the first time, reported aneuploidy in blood of exposed workers characteristic of myeloid leukaemia and myelodysplastic syndromes, with supporting information suggesting a decrease in the major circulating blood-cell types and in circulating haematological precursor cells. The authors and Working Group felt that this study needed to be replicated. Formaldehyde is carcinogenic to humans (Group 1).

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: http://monographs.iarc.fr/ENG/Classification/index.php p. V100F 430 (2012)] **PEER REVIEWED**

Cancer Classification: Group B1 Probable Human Carcinogen

[USEPA Office of Pesticide Programs, Health Effects Division, Science Information Management Branch: "Chemicals Evaluated for Carcinogenic Potential" (April 2006)] **PEER REVIEWED**

CLASSIFICATION: B1; probable human carcinogen. BASIS FOR CLASSIFICATION: Based on limited evidence in humans, and sufficient evidence in animals. Human data include nine studies that show statistically significant associations between site-specific respiratory neoplasms and exposure to formaldehyde or

formaldehyde-containing products. An increased incidence of nasal squamous cell carcinomas was observed in long-term inhalation studies in rats and in mice. The classification is supported by in vitro genotoxicity data and formaldehyde's structural relationships to other carcinogenic aldehydes such as acetaldehyde. HUMAN CARCINOGENICITY DATA: Limited. ANIMAL CARCINOGENICITY DATA: Sufficient.

[U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS). Summary on Formaldehyde (50-00-0). Available from, as of December 15, 2014: http://www.epa.gov/iris/ **PEER REVIEWED**

A2; Suspected human carcinogen.

[American Conference of Governmental Industrial Hygienists. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. ACGIH, Cincinnati, OH 2014, p. 32] **PEER REVIEWED**

Formaldehyde: Known to be a human carcinogen.

[DHHS/National Toxicology Program; Thirteenth Report on Carcinogens: Formaldehyde (50-00-0) (2014). Available from, as of December 12, 2014: http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html **PEER REVIEWED**

Three out of the five data points identified above are Step I sources although the conclusion from the American Conference of Governmental Industrial Hygienists TLVS and EPA's Pesticide Program are not. These sources were reviewed by experts and deemed worthy for inclusion. Additional sources like this might prove useful for other chemicals not identified in Step I sources.

Searching HSDB: An easier method for locating information in the HSDB is to click on the complete record for the chemical being evaluated. This record can then be searched (by pressing the Control key and 'F' simultaneously) to search out pertinent information for each hazard criteria. Ecology has found the following keywords (or any portion thereof) useful in evaluating data contained in the HSDB:

- Carcinogenicity
- Mutagenicity
- Genotoxicity (used to report mutagenicity results)
- Reproduction
- Developmental

Other keywords may assist in this process.

For example, the full HSDB record for formaldehyde was searched for reproductive hazards using just the fragment 'reprod' in the Control F method described above. The following information was located:

0.2.19.2 CHRONIC EXPOSURE A) Allergic contact dermatitis, eczema, and other signs have been attributed to formaldehyde sensitivity. 0.2.20 REPRODUCTIVE HAZARDS Formaldehyde has not been shown definitely to be teratogenic in animals. Formaldehyde probably presents little or no risk as a potential human teratogen. Menstrual disorders have been reported in women occupationally exposed to formaldehyde, but these results are controversial. In experimental animal studies, some effects on spermatogenesis have been reported. C) Occupational exposure at recommended limits is not thought to present a reproductive risk. Formaldehyde exposure among female hospital workers did not correlate with an increase in spontaneous abortion in one study, but did correlate in another. Low-birthweight children have been reported in female workers exposed to urea-formaldehyde resin, but studies are inconclusive. Formaldehyde appears to cross the placental barrier in mice.

0.2.21 CARCINOGENICITY 0.2.21.1 IARC CATEGORY

- A) IARC Carcinogenicity Ratings for CAS50-00-0 (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2006; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010a; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2008; IARC, 2004):
- 1) Not Listed
- 0.2.21.2 HUMAN OVERVIEW

Information in this area could be used to fill in the box for reproductive toxicity. Specifically:

• Reproductive toxicity: 'Menstrual disorders have been reported in women occupationally exposed...' and '... did not correlate with an increase in spontaneous abortion in one study, but did correlate in another.' and 'Low-birthweight children have been reported in female workers.... but studies are inconclusive... appears to cross the placental barrier in mice.'

This responds to 'indication of repro/developmental toxicity' and would qualify as a 'moderate' level of concern.

The same formaldehyde record was searched for information on genotoxicity using the fragment 'genot'. The following information resulted:

0.2.21.3 ANIMAL OVERVIEW

- A) An increased incidence of nasal squamous cell carcinomas was observed in long-term inhalation studies in rats and in mice. The classification of B1 is further supported by in vitro genotoxicity data and formaldehyde's structural relationships to other carcinogenic aldehydes such as acetaldehyde.
- 0.2.22 GENOTOXICITY
 - A) Formaldehyde appears to be mutagenic. The basis for its genetic activity is its ability to form cross-links in DNA and proteins.
 - B) Formaldehyde is a potent genotoxin and has been reported to be active in many short-term genetic tests, including the Ames Salmonella assay and other assays for mutation using bacteria, chromosome aberrations and sister chromatid exchanges in vitro and in vivo, and many assays detecting direct effects on DNA.

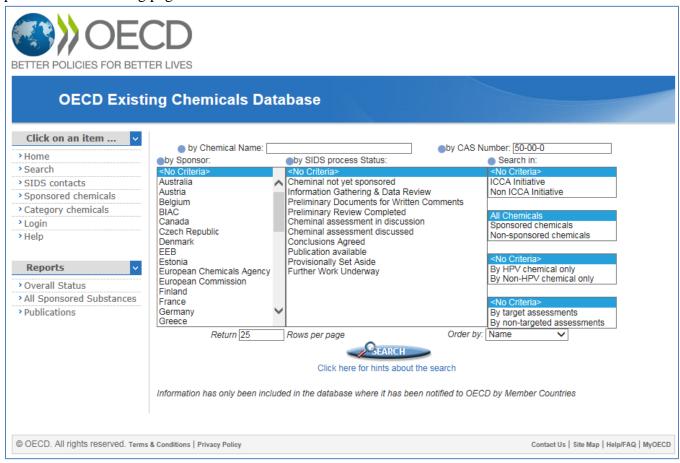
This information indicates that formaldehyde has a 'high' level of concern for mutagenicity/genotoxicity. Specifically:

- 'Formaldehyde appears to be mutagenic.'
- Formaldehyde is a potent genotoxin and has been reported to be active in many short-term genetic tests....'

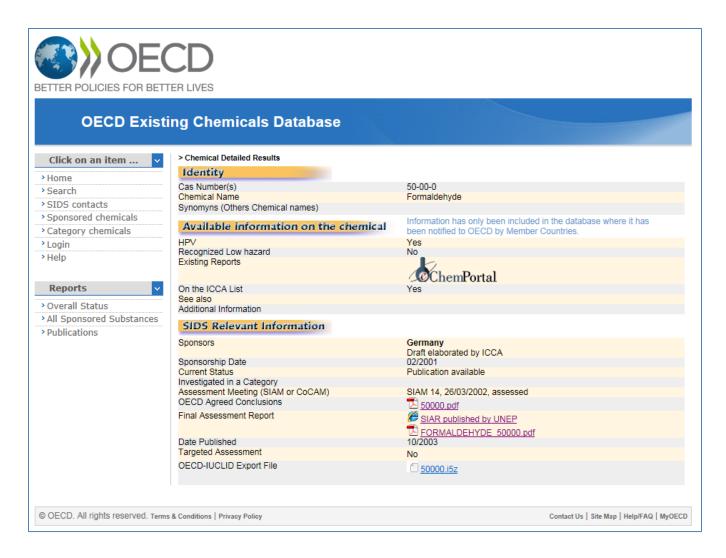
By conducting searches like this, the full HSDB record can be evaluated and information pertinent to assessing specific hazard endpoints can be located. Information may be embedded in the full record and may not be obvious. It is important to remember that this data would only be necessary if mutagenicity/genotoxicity or reproductive toxicity are not covered by a Step I authoritative source.

6. United Nations Environmental Program Safety Information Datasheets (UNEP SIDS)

The UNEP SIDS are made available through the Organization for Economic Cooperation and Development (OECD) Existing Chemicals Database. Clicking on the link in the QCAT Checklist, presents the following page:



The QCAT assessor may search by name or CAS number. As a CAS number is required to use QCAT, searching by CAS is recommended. Entering the CAS number for formaldehyde (50-00-0) as an example and hitting the 'search' button leads to the following:



In this example, the link for the UNEP document was broken. However, the report beneath it labeled 'FORMALDEHYDE 50000.pdf' links to the OECD SIDS, which is a publication of the UNEP.

Like the EU RAs mentioned previously, SIDS often review available data in detail and reach a conclusion. The QCAT assessor should search for the conclusions to determine if the results may be useful in conducting a QCAT assessment. For example, the formaldehyde SIDS reviews extensive data on formaldehyde's effect on aquatic toxicity. The summary at the end of the session states:

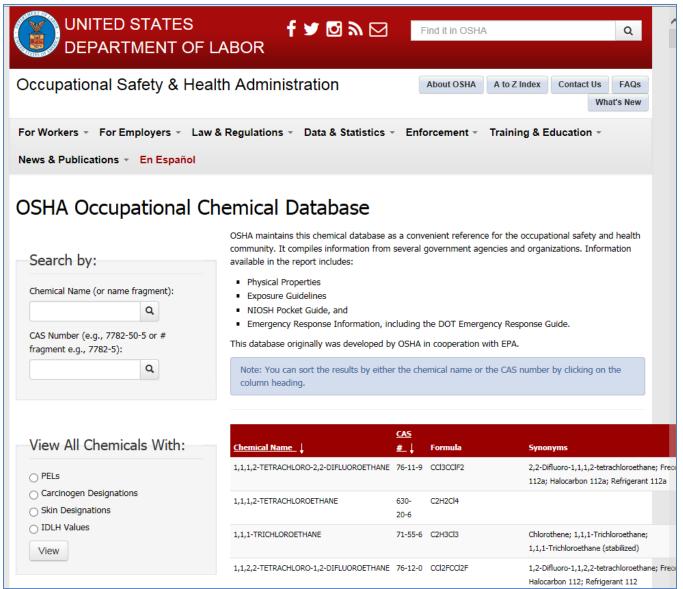
Conclusions on Aquatic effects

Distribution modelling estimates water to be the main target compartment for formaldehyde. The most sensitive organism in an valid acute aquatic toxicity test was Daphnia pulex with an EC50 (48 h) of 5.8 mg/l.....

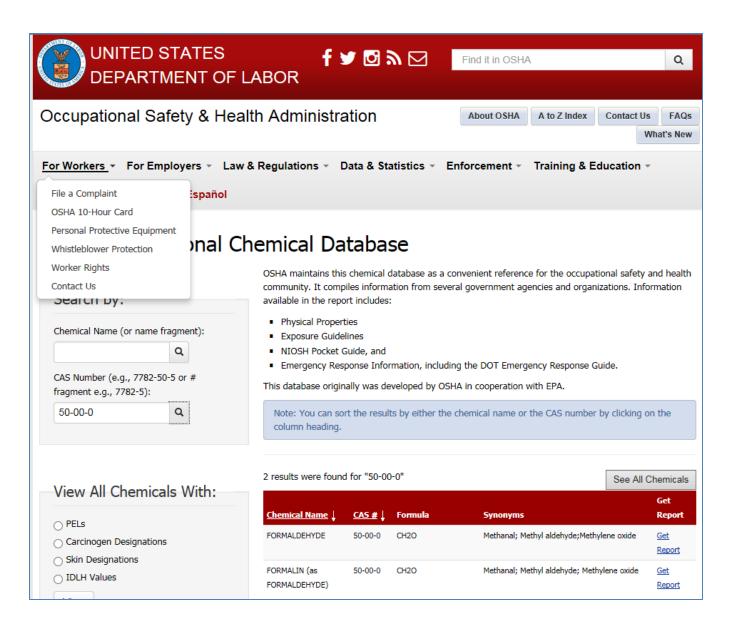
The EC₅₀ value listed here could be compared against Technical Criteria in Appendix 8 to determine a acute aquatic toxicity concern for formaldehyde.

7. Occupational Safety & Health Administration (OSHA) Chemical Database (OCD)

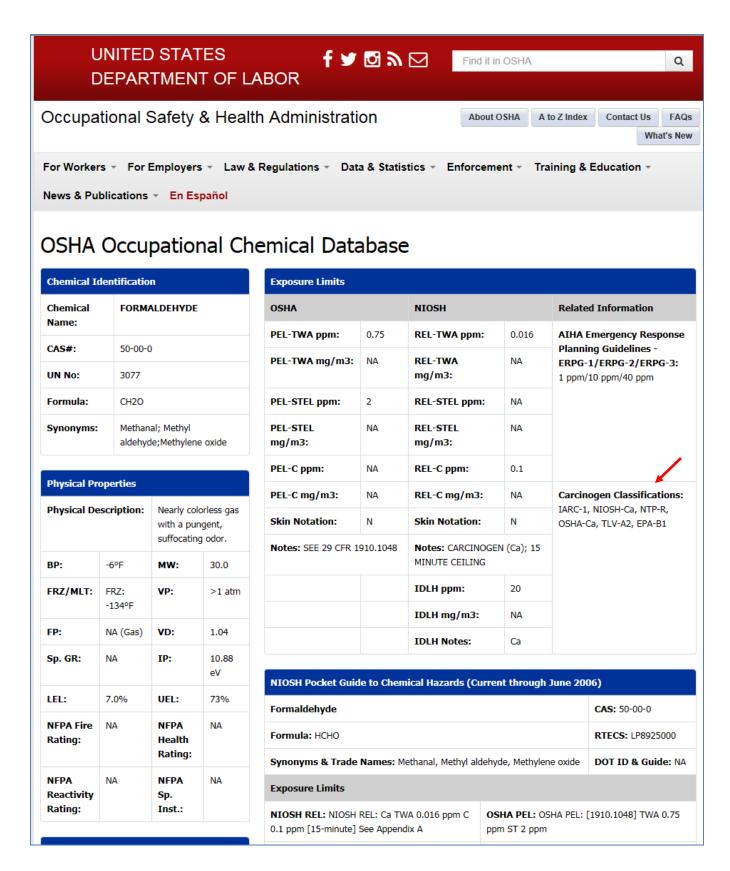
The OCD contains information on the potential exposure concerns related to worker health and safety. Although the acute toxicity information requires considerable technical expertise, the OCD does identify chemicals as potential carcinogens. Clicking on the link provided in the QCAT Checklist, this page appears:



The QCAT assessor can search by chemical name or CAS. Entering in the CAS for formaldehyde as an example, leads to the following page:



Clicking on the 'Get Report' for formaldehyde, leads to the following results:



Note: This is an abbreviated capture of the data shown. More data is available although it is likely to be of minimal use to the QCAT assessor.

Information of interest is the information in the box labeled 'Carcinogen Classifications' (red arrow) which identifies if there are any carcinogenicity concerns associated with the chemical of interest. Although much of the information on carcinogenicity for formaldehyde is pulled from sources used in Step I, additional information on the carcinogenicity classification for chemicals not identified in Step I sources may prove useful in completing a QCAT evaluation.

8. Danish Ministry of the Environment's Environmental Protection Agency (Danish EPA) (Q)SAR Assessment of Chemical Properties of Substances

The Danish EPA has created a database that contains predictions on the potential toxicity of approximately 166,000 chemicals. The database predicts toxicity for the following criteria of importance to the QCAT:

- Mutagenicity
- Carcinogenicity
- Reproductive toxicity

- Aquatic environment
- Acute human (oral) toxicity

For the purposes of the QCAT, the full (Q)SAR database will not be used but a subset of more than 30,000 substances for which GHS classifications have been estimated and are reported in the Danish Advisory List for Self-Classification. These GHS results are directly comparable to the GHS criteria included in the Appendix 8 of QCAT.

The link available in the QCAT Checklist leads the assessor to the following page:

The advisory list for self classification of dangerous substances

Lack of data on hazardous properties of chemicals makes it difficult for companies to meet their obligations to self classify the chemicals they import or produce. To address this issue, The Danish Environmental Protection Agency (DK-EPA) publishes two lists for self classification of chemical substances" - with advisory classifications of more than 30,000 substances.

Since the new regulation for classification and labelling (the CLP-regulation) came into force, the regulation is in a transitional phase until 2015 where both regulations still are relevant in certain situations. Therefore both regulations are covered.

How to use the list

The advisory classifications are based on predictions of dangerous properties of chemicals from computer models - the so-called (Q)SARs - which has a built-in uncertainty. Statistical methods estimate that the proposals are correct in approx. 80% of the cases. Therefore, in relation to self-classification of chemicals, the Danish Environmental Agency recommends that:

- If a substance has an EU-harmonised classification, then this harmonised classification must be followed and the advisory classification should be neglected.
- All reliable information (test data and other types of information) must be considered together with the advisory classifications using a weight of evidence based approach.
- In those cases where no reliable information is available for a substance, the advisory classification can be used alone.
- It is further strongly recommended to read the additional information on selfclassification and the advisory lists carefully before using the list (see below).

Search the advisory list for self classification of chemical substances.

<u>Database where you can search the list of advisory CLP-classifications.</u>

<u>Excel sheet with advisory CLP-classifications</u>

<u>Database with advisory classifications according to the old regulation</u>

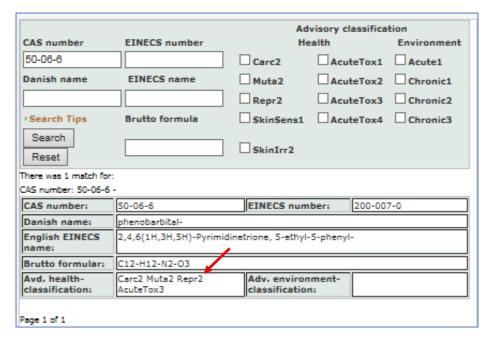
<u>Excel-sheet with with advisory classifications according to the old regulation.</u>

The QCAT assessor can either search the database or download an excel spreadsheet. There are two legislations for which this information was created. Both can be reviewed although the data for the CLP classifications is likely to be the most valuable.

If the assessor clicks on the CLP database link (red arrow above), the following page appears:

to access the database where you can search the list of advisory CLPclassifications Advisory classification CAS number EINECS number Environment 50-06-6 Carc2 ☐ AcuteTox1 ☐ Acute1 Danish name EINECS name ☐ Muta2 AcuteTox2 Chronic1 Repr2 AcuteTox3 Chronic2 Brutto formula SkinSens1 AcuteTox4 Chronic3 Search Tips Search SkinIrr2 Reset Search Tips Enter information in one or more boxes and press Search. . If you wish to make a search based on more than one criteria fill in data in two or more boxes. If you type the beginning of a CAS number and/or a EINECS number, all matters beginning with this number will appear on the list of results. As an example: if the number 20 is entered in the EINECS number box, only matters with an EINECS number beginning with 20 will be on the list of found matters. . If you wish to search for a certain number included in a CAS or an EINECS number e.g. in the middle of the EINECS number, it is necessary to enter % and then the number. If you enter %15 in the EINECS number box, all matters including the number 15 will appear on the list of found If you enter text in the Danish name box, EINECS name box and/or Brutto formula box, the list of results will show all matters that include the text whether represented in the beginning, the middle or the end of the name. In Advisory classification you can limit your search by checking one or more boxes.

In this instance, our previous example chemical (formaldehyde) would not work since formaldehyde's impacts upon human health and the environment are well documented. However, another chemical, phenobarbital (CAS 50-06-6) is used as an example and the database searched leading to the following:



Based upon the predictive capabilities of the models used, phenobarbital is identified (red arrow) as a Category 2 carcinogen (Carc2), mutagen (Muta2) and reproductive toxicant (Repr2) and a Category 3 acute mammalian toxic (AcuteTox3). These values can be compared against the criteria in Appendix 8 and identified a level of concern for this chemical of concern.

The QCAT assessor may also download an Excel spreadsheet. Using phenobarbital again as an example, the following information is found:

| Adviso | ory Cl | | |
|---------------------|---------|-------------------------------|--|
| Danis l | h Env | | |
| Further information | on: | | |
| Publication date: | | | |
| CASN | CAS | CLP vejledende klassificering | |
| 50044 | 50-04-4 | Repr2 AcuteTox4 | |
| 50066 | 50-06-6 | Carc2 Muta2 Repr2 AcuteTox3 | |
| 50077 | 50-07-7 | Carc2 Muta2 Repr2 AcuteTox2 | |
| 50000 | 50.00.0 | AcutoTov4 | |

Column 7 of the spreadsheet contains the hazard assessment results, which agree with the information provided in the database. The spreadsheet indicates there are 33,835 chemicals in the database so, for those chemicals lacking important data, this database might help fill in many datagaps.

9. Ecological Toxicity (ECOTOX) Database

ECOTOX is a major source of ecological toxicity information. However, unlike many of the previous sources, EPA does not conduct detailed technical review of all of the information included in ECOTOX. There will be more variability in the quality of data found within. To address this concern, a 'weight of evidence' approach will be used to identify values to be used in a QCAT evaluation. In addition, the exposure hierarchy described in the HSDB section above (Salmonids followed by fathead minnow, followed by any other fish species) will be used during data evaluation.

The ECOTOX opening page appears as follows:



ECOTOX Database

Recent Additions | Contact Us Search: OAII EPA This Area

You are here: EPA Home » ECOTOX



Quick Database Query

Advanced Database Query

Data Downloads

Browse Chemicals

Browse Effects Browse

Send Comments

Species

Quick Database Query



Go

Welcome to ECOTOX Release 4.0. The ECOTOX (ECOTOXicology) database provides single chemical toxicity information for aquatic and terrestrial life.

For information on the latest data releases please see the Recent Additions.

View the Quick User Guide (PDF, 2 p. 244 KB) to help get you started.

You will need to turn off pop-up blockers for this site.

You should consult the original scientific paper to ensure an understanding of the context of the data retrieved from the ECOTOX database.

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Other Tools & Databases

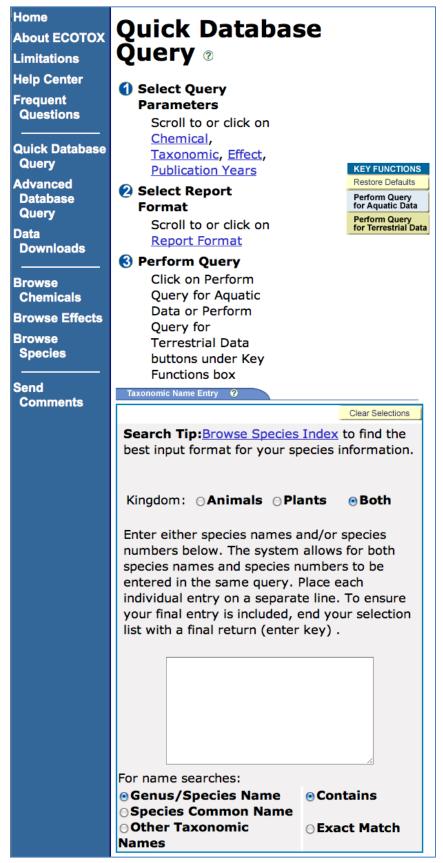
- ASTER
- BSAF data set
- Eco-SSL documents
- Fathead Minnow data set
- PCB Residue Effects data set
- Toxicity/Residue

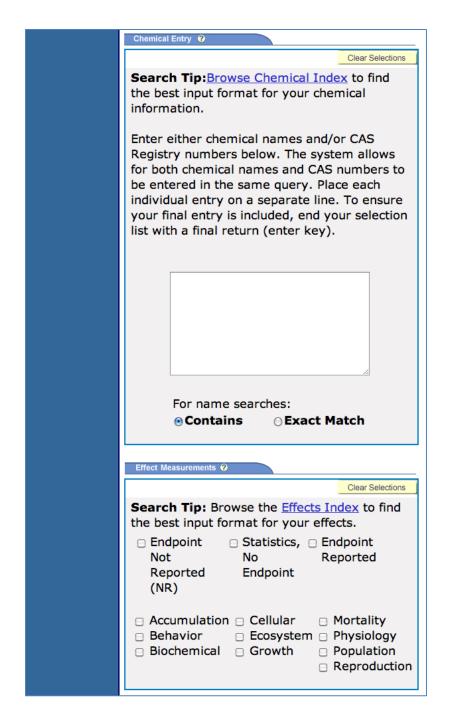
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Last updated on March 3, 2014

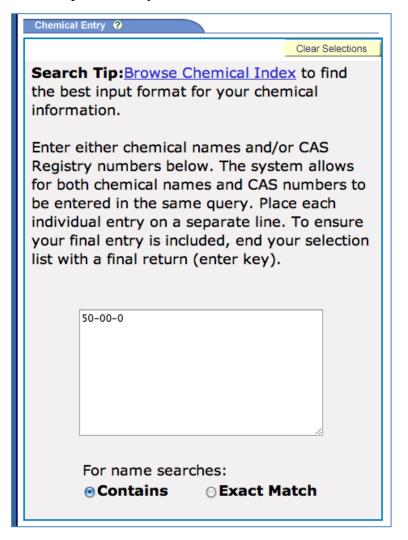
The easiest way to request information from the database is to select the 'Quick Database Query' Option' which, once selected, appears as:





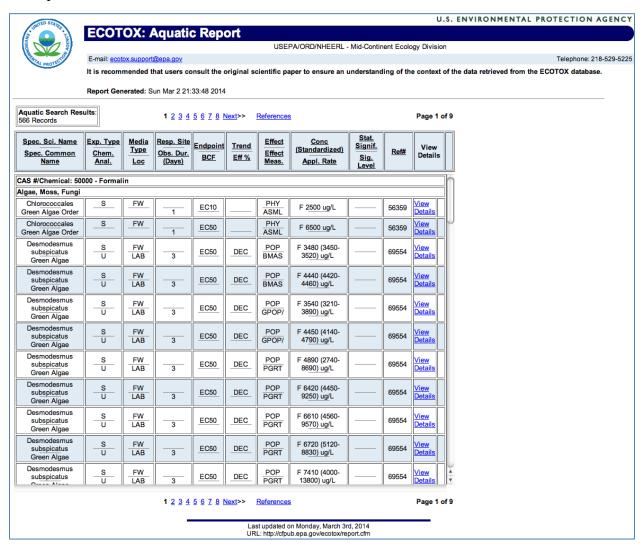
The screen captures above represent part of the information on the page. As can be seen, there are numerous ways to request data from ECOTOX. For most chemicals, there is limited information and the simplest method will work. In this instance, you enter the CAS number in the box labeled 'Chemical Entry.' No other changes are needed.

Using formaldehyde as an example, the entry would look like this:



Once the CAS number is entered into this box, the assessor clicks on the 'Perform Query for Aquatic Data.' A separate window will open that lists all of the information available in ECOTOX.

For example:



Formaldehyde contains numerous acute aquatic toxicity (LC₅₀) entries for Rainbow Trout. An excerpt of this data follows on the next page.

| Spec. Sci. Name Spec. Common Name | Chem. Anal. | Media Type Loc | Resp. Site Obs. Dur. (Days) | Endpoint BCF | Trend Eff % | Effect Meas. | Conc (Standardized) Appl. Rate | Stat. Signif. Sig. Level | Ref# | View Details | • |
|---|----------------|----------------------|-----------------------------|-----------------|----------------|-----------------|--------------------------------------|-----------------------------------|-------|-------------------------------|---|
| Oncorhynchus mykiss Rainbow Trout | FU | FW LAB | 0.333 | _LC50_ | INC | MOR MORT | F 0.223 (0.128- 0.318) ml/L | | 16992 | View Details | _ |
| Oncorhynchus mykiss Rainbow Trout | FU | FW LAB | 1 | LC50 | INC | MOR MORT | F 0.162 (0.081- 0.243) ml/L | | 16992 | <u>View</u> <u>Details</u> | |
| Oncorhynchus mykiss Rainbow Trout | FU | FW LAB | | _LC50 | INC | MOR MORT | F 0.159 (0.011- 0.247) ml/L | | 16992 | View Details | |
| Oncorhynchus mykiss Rainbow Trout | FU | FW LAB | 3 | _LC50_ | INC | MOR MORT | F 0.149 (0.059- 0.239) ml/L | | 16992 | View Details | |
| Oncorhynchus mykiss Rainbow Trout | F U | FW LAB | 4 | _LC50_ | INC | MOR MORT | F 0.129 (0.032- 0.226) ml/L | | 16992 | <u>View</u> <u>Details</u> | |
| Oncorhynchus mykiss Rainbow Trout | | FW LAB | | _LC50_ | _INC_ | MOR MORT | F 50000 (42300- 86000) ug/L | | 18459 | View Details | |
| Oncorhynchus mykiss Rainbow Trout | RU | FW LAB | | _LC50_ | INC | MOR MORT/ | F 32 <u>0000 ug</u> /L | | 6573 | <u>View</u> <u>Details</u> | |
| Oncorhynchus mykiss Rainbow Trout | | FW LAB | 4 | _LC50_ | | MOR MORT | NC > 100000 ug/L | | 344 | <u>View</u> <u>Details</u> | |
| Oncorhynchus mykiss Rainbow Trout | | FW LAB | 4 | _LC50_ | | MOR MORT | NC > 100000 ug/L | | 344 | View Details | |
| Oncorhynchus mykiss Rainbow Trout | | FW LAB | 4 | _LC50 | | MOR MORT | NC 118000 (99700-140000) _ug/L | | 344 | View Details | |
| Oncorhynchus mykiss Rainbow Trout | | FW LAB | 4 | LC50 | | MOR MORT | NC 118000 (99700-140000) ug/L | | 344 | View Details | |

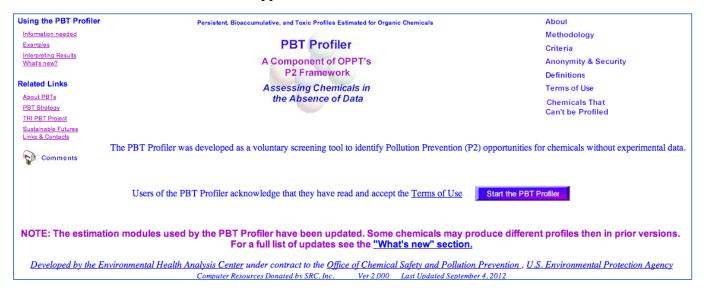
Many of the LC₅₀ results can be discarded because the test lasted less than 24 hours (0.333 days). The remaining tests which lasted anywhere from 1 to 4 days provided results ranging from 1,410 to 320,000 μ g/L. However, the low values were found in a limited number of studies and a majority of the results were in the 100,000 to 200,000 μ g/L range. Therefore a value of 150,000 micrograms per liter (equivalent to 150 mg/L) would be selected for the QCAT as being most representative of the data in ECOTOX.

ECOTOX also contains information on a chemical's bioaccumulation factor. As with other information, the user must determine which BCF values to use. A 'weight of evidence' approach as shown in other examples in this document might be a preferred method. However, if bioaccumulation information cannot be found in the other sources or confirmatory values are needed, ECOTOX may prove a valuable source to determine whether or not a chemical bioaccumulates.

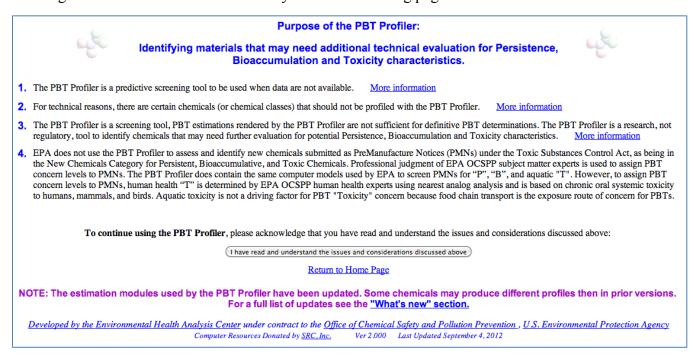
10. PBT Profiler

The U.S. EPA has developed a system for assessing chemicals for persistence and bioaccumulation when experimental data are absent. This system, the PBT Profiler, is used as screening tool to estimate persistence and bioaccumulation criteria and should only be used when other sources of information are not available.

The initial screen of the PBT Profiler appears as:



Clicking on 'Start the PBT Profiler' takes you to the following page:



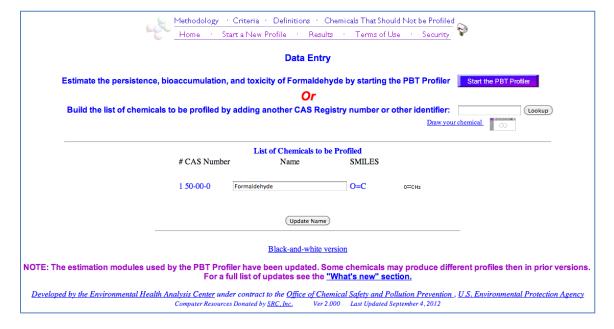
Agreeing to the issues and considerations takes you to the following page:



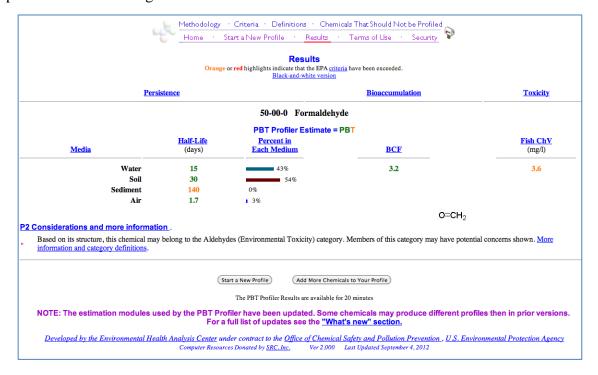
You may now actually start the PBT Profiler.



Using formaldehyde as an example, enter its CAS number into the box and click on 'Lookup'. The following page appears:



Search for data on multiple chemicals by entering information on a second chemical and pressing 'Lookup' or look at the report on a single chemical by selecting the 'Start the PBT Profiler' option, which produces the following:



Various media including water, soil, sediment, and air display persistence results. When considering whether a chemical is persistent, it would be appropriate to consider what media is mostly likely to be the major factor for the chemical under evaluation. In the case of formaldehyde, the half-life values for water and soil are most important as these two media account for 97% of the media in which it is distributed. Sediment and air comprise only 3% and their half-life values are less likely to impact whether or not formaldehyde is persistent.

In addition to persistence, the PBT Profiler also includes information on bioaccumulation and toxicity. The bioaccumulation tendency is displayed as a projected bioaccumulation factor (BCF). This information may prove useful in filling in any gaps that remain for these criteria. The toxicity values, however, cannot be translated into a level of concern in QCAT using the DfE criteria and therefore are unlikely to help in the chemical assessment.

11. US EPA Characterization Criteria

As part of EPA's New Chemical Program, hazard endpoints were parsed into various levels of concern to assist EPA to better identify chemicals which may negatively impact human health or the environment. These criteria are used by EPA's Design for the Environment Program to assign a level of concern while conducting a chemical hazard assessment and were subsequently incorporated into the GreenScreen and QCAT methodologies.

The link provided in the QCAT Checklist takes the assessor directly to the criteria used by EPA's Design for the Environment Program (DfE) during their chemical hazard assessment process in support of their Alternatives Assessment Program. As DfE states:

For most endpoints, the criteria define "High," "Moderate," and "Low" concern. While many hazard classification criteria exist throughout the world, DfE has carefully chosen the criteria that form the Alternatives Assessment Criteria for Hazard Evaluation with the goal of creating a rigorous and useful system for differentiating among chemicals based on hazard. Authoritative sources — the United Nation's Globally Harmonized System (GHS) for the Classification and Labeling of Chemicals and U.S. EPA programs — are the basis for these distinctions. The criteria include endpoints used in the Screening Information Data Set (SIDS) [1], a set of endpoints internationally agreed upon for characterizing chemical hazards. In assigning a designation of Low, Moderate, or High concern for hazard, DfE uses the best information available, both experimental and modeled.

Unlike the previous Step II sources, there is no actual data here that can help a QCAT assessor assign a level of concern for a chemical being evaluated. It was deemed important, however, that the QCAT explain the source of the Technical Criteria found in Appendix 8 to show that considerable thought had gone into separating data into different levels of concern.

Appendix 3: Example Hazard Comparison Table

Data found:

| Chem. | CAC | | Humar | ո Health - Group | 1 | | | Huma | n Hea | lth - Gro | oup 2 | | | Ecolog | gical | | Fa | Physical | | |
|-------|-----------|---------------------|-------------------------|------------------------|--------------------|--------------|---------------------------------------|------|-------|-----------|-------|-----|-----|-------------------------------------|-------|----|---------------------------------|-------------------|----|---|
| Cnem. | CAS | С | M | R | D | E | AT | ST | N | SnS | SnR | IrS | IrE | AA | CA | Eo | P | В | Ex | F |
| 1 | 1234-56-1 | IRIS 1986 Cat. A | GHS Cat. 2 | GHS Risk R62 | Prop 65 on list | EU Cat. 1 | Oral LD ₅₀ = 25mg/kg | | | | | | | Fish LC ₅₀ = 0.5mg/L | | | Soil t _{1/2} = 2,000d | WA PBT on list | | |
| 2 | 1234-56-2 | IRIS 1986 Cat. E | Meets DfE low Screen | Oral LOAEL = 500 mg/kg | EU RA no sign | No Data | Oral LD ₅₀ = 3000 mg/kg | | | | | | | Oral LD ₅₀ = 3,000 mg/kg | | | Soil t _{1/2} = 25 d | BCF = 560 | | |
| 3 | 1234-56-3 | IARC Group 4 | Risk Phrase R 47 | No Data | Risk PhraseR62 | No Data | DG | | | | | | | GHS Cat. 3 | | | No Data | EU RA No B | | |

Summary based upon existing data:

| Chem. | CAS | Hun | nan H | Iealth | - Gro | up 1 | | Hum | an E | Iealth | - Grou | ıp 2 | | Ec | ologic | al | Fate | | Physical | |
|-------|-----------|-----|-------|--------|-------|------|----|-----|------|---------------|--------|------|-----|----|--------|----|------|----|----------|---|
| Chem. | CAS | C | M | R | D | E | AT | ST | N | SnS | SnR | IrS | IrE | AA | CA | Eo | P | В | Ex | F |
| 1 | 1234-56-1 | H | M | M | H | H | vH | | | | | | | H | | | vH | vH | | |
| 2 | 1234-56-2 | L | L | L | L | DG | L | | | | | | | L | | | L | M | | |
| 3 | 1234-56-3 | L | M | DG | M | DG | DG | | | | | | | L | | | DG | L | | |

Gray box = $GS^{\textcircled{\$}}$ criteria not used in QCAT

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at

www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

Appendix 4: Grading Process

| Grade A | a. Low P + Low T (AA, AT and all HH endpoints). |
|---------|--|
| Grade B | a. Moderate P; or b. Moderate B; or c. Moderate AA; or d. Moderate AT or one or more HH endpoints. |
| Grade C | a. Moderate P + Moderate B + Moderate T (AA, AT, or one of the HH endpoints); or b. High P + High B; or c. High P + Moderate T (AA, AT, or any one of the HH endpoints); or d. High B + Moderate T (AA, AT, or any one of the HH endpoints); or e. Very High T (AA or AT) or High T (any one of the HH endpoints). |
| Grade F | a. PBT = High P + High B + [Very High T (AA or AT) or High T (HH)]; or b. vPvB = very High P + very High B; or c. vPT = very High P + [very High T (AA or AT) or High T (HH)]; or d. vBT = very High B + [very High T (AA or AT) or High T (HH)]; or e. High T (HH). |

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/Green Chemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

¹Legend:

| $\mathbf{A}\mathbf{A}$ | = | Acute Aquatic Toxicity | D | = | Developmental Toxicity (incl. developmental neurotoxicity) | M | = | Mutagenicity/Genotoxicity |
|------------------------|---|--------------------------|--------------|---|--|------------------------|---|---------------------------|
| AT | = | Acute Mammalian Toxicity | \mathbf{E} | = | Endocrine Activity | R | = | Reproductive toxicity |
| В | = | Bioaccumulation | F | = | Flammability | $\mathbf{v}\mathbf{B}$ | = | Very Bioaccumulative |
| \mathbf{C} | = | Carcinogenicity | HH1 | = | Human Health Group 1 (C, M/G, R, D & E) | vP | = | Very Persistent |
| | | | HH2 | = | Human Health Group 2 (AT) | | | |

Note: The assignment of grades is based upon the benchmarking process described in the GS^{\otimes} . The GS^{\otimes} benchmarking process was formulated during extensive discussions with nationally recognized experts in the various hazard criteria. These experts functioned as the Technical Advisory Committee during the update and expansion of the GS^{\otimes} Version 1.2. The intent of this discussion, however, was to provide a reproducible method of assigning degrees of concern based upon the results of the GS^{\otimes} assessment. For the purposes of the QCAT, a similar process is used as found in the GS^{\otimes} after the seven hazard criteria not used in the QCAT have been removed.

Appendix 5: Result of Final QCAT Evaluation for Chemicals in Appendix 3

| Chemical | End Use | | Grades | | Reasons for Grade |
|------------|-----------------|------------|---|--------------------------|---|
| Chemical | End Ose | Initial | Data Gap | Final | Reasons for Grade |
| Chemical 1 | Flame Retardant | Grade F | N/A | Grade F | Very high acute mammalian toxicity, high persistence and bioaccumulation. High for three of the human health endpoints and high acute aquatic toxicity. A data gap analysis is not required as all endpoints have data. |
| Chemical 2 | Flame Retardant | Grade B | Grade B | Grade B | Grade B based upon low human hazard endpoints, low AT and moderate B and low P. There is no change to the initial grade as only one data gap exists and it is not for a required endpoint. |
| Chemical 3 | Flame Retardant | Grade C | $\begin{matrix} \textbf{Grade} \\ \textbf{F}_{\tt dg} \end{matrix}$ | Grade F _{dg} | Grade C due to moderate mutagenicity/genotoxicity and developmental toxicity. Data gaps exist for four criteria including a required endpoint (P). Grade 'F _{dg} ' assigned showing lack of confidence in grade assigned based upon existing data. |

| Grade A | Few concerns, i.e., safer chemical | Preferable |
|---------|------------------------------------|--------------------------|
| Grade B | Slight concern | Improvement possible |
| Grade C | Moderate concern | Use but search for safer |
| Grade F | High concern | Avoid |

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

Appendix 6: QCAT Blank Report

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

QCAT Evaluation: Peer review: **Author: Reviewer:** Title: Title: Organization: Organization:

Date: Date:

QCAT for Safer Chemicals Example Chemical Assessment Worksheet

Chemical Name:

CAS #:

Also Called:

Identify Applications/Functional Uses:

Molecular Formula:

Molecular Weight:

Chemical Structure:

Optional Physicochemical Properties: Delete row if not used

Hazard Summary Table:

| Hum | an Hea | lth Gro | oup 1 (I | HH1) | Hu | ıman | Hea | alth G | roup 2 | (HH | 2) | Ec | al | Fa | ite | Physical | | |
|-------|---|---------|----------|------|----|------|-----|--------|--------|-----|-----|----|----|----|-----|----------|----|---|
| C | M | R | D | E | AT | ST | N | SnS | SnR | IrS | IrE | AA | CA | Eo | P | В | Ex | F |
| | | | | | | | | | | | | | | | | | | |
| Note: | Note: Please see Appendix A for glossary of hazard endpoint acronyms. | | | | | | | | | | | | | | | | | |

| | Grades | |
|---------|----------|-------|
| Initial | Data Gap | Final |
| | | |
| | | |

Human Health Effects - Group I

Carcinogenicity (C) Hazard Level (H, M, L or DG):

- Research Summary:
- References:

Mutagenicity and Genotoxicity (M) Hazard Level (H, M, L or DG):

| Research Summary: |
|---|
| • References: |
| Reproductive Toxicity (R) Hazard Level (H, M, L or DG): Research Summary: |
| • References: |
| Development Toxicity incl. Developmental Neurotoxicity (D) Hazard Level (H, M, L or DG): ■ Research Summary: |
| • References: |
| Endocrine Disruption (E) Hazard Level (H, M, L or DG): Research Summary: |
| • References: |
| Human Health Effects – Group II Acute Mammalian Toxicity (AT) Hazard Level (vH, H, M, L or DG): ■ Research Summary: |
| • References: |
| Environmental Health Effects Acute Aquatic (AA) Toxicity Hazard Level: (VH, H, M, L or DG): Research Summary: |
| • References: |
| Environmental Fate Persistence (P) Hazard Level: (VH, H, M, L, VI or DG): Research Summary: |
| References: |
| Bioaccumulation (B) Potential Hazard Level: (VH, H, M, L, VI or DG): Research Summary: |
| • References: |

Appendix 7: Example of a Completed QCAT Report

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

QCAT for Safer Chemicals Example Chemical Assessment Worksheet

Chemical Name: Tetrachloroethylene

CAS Registry Number: 127-18-4

Also Called: Perc; PERC; Ethylene, tetrachloro-

Identify Applications/Functional Uses: Dry cleaning solvent

Molecular Formula: C₂Cl₄
Molecular Weight: 165.82

Chemical Structure:

$$C1$$
 $C1$ $C1$

Hazard Summary Table:

| Hui | man F | lealth (HH1) | | up 1 | H | uman | Не | alth G | roup 2 | 2 (HH | Ec | ologic | al | Fat | te | Physical | | |
|---|-------|-----------------|---|------|----|------|----|--------|--------|-------|-----|--------|----|-----|----|----------|----|---|
| C | M | R | D | E | AT | ST | N | SnS | SnR | IrS | IrE | AA | CA | Eo | P | В | Ex | F |
| H | M | M | M | M | M | | | | | | | vH | | | vH | L | | |
| Note: Please see Appendix A for glossary of hazard endpoint acronyms. | | | | | | | | | | | | | | | | | | |

| Grades | | | |
|------------------------|----|---|--|
| Initial Data Gap Final | | | |
| F | NA | F | |

Although data was limited for some hazard endpoints, a level of concern could be assigned to perchloroethylene (PERC) for all nine QCAT hazard endpoints. Based upon this data, PERC was identified as a carcinogen due to listings by a number of authoritative bodies including the US NIH's Report on Carcinogens, IARC's identification as a probable carcinogen, appearance on the California EPA's Prop 65 list as a carcinogen, etc. Using QCAT grading criteria, PERC meets the CMR (carcinogenic, mutagenic or reproductive toxicant) criteria (Grading Criteria F5) and is assigned an Initial Grade F. As no data gaps were identified and a data gap analysis is not required for any chemical assigned an Initial Grade F, PERC was assigned a Final Grade of F.

Human Health Effects – Group I

Carcinogenicity (C) Hazard Level (H, M, L or DG): H

Research Summary: Tetrachloroethylene appears on nine authoritative lists and sources such as the US NIH's Report on Carcinogens, IARC's identification as a probably carcinogen, appearance on the California EPA's Prop 65 list as a carcinogen which equated to a high level of concern. Tetrachloroethylene was assigned a moderate level of concern by three additional authoritative sources. Based upon the determinations by organizations such as IARC, NIH and California EPA and the preponderance of the organizations assigning a high level of concern, perchloroethylene was assigned a **HIGH** level of concern.

References:

Pharos:

High level of concern:

- US Environmental Protection Agency Integrated Risk Information System Database (IRIS) (2005) Likely to be carcinogenic to humans. This equates to a HIGH level of concern in the QCAT methodology.
- International Agency for Research on Cancer, World Health Organization *Monographs On the Evaluation of Carcinogenic Risks to Humans*, Group 2A: Agent is probably carcinogenic to humans. This equates to a HIGH level of concern in the QCAT methodology.
- **US Dept of Health & Human Services** *Report on Carcinogens* Reasonably Anticipated to be Human Carcinogen. This equates to a HIGH level of concern in the QCAT methodology.
- State of California Environmental Protection Agency Chemicals Known to the State to Cause Cancer or Reproductive Toxicity California Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986 Cancer. This equates to a HIGH level of concern in the QCAT methodology.
- **US Centers for Disease Control** *NIOSH Carcinogen List* Occupational carcinogen. This equates to a HIGH level of concern in the QCAT methodology.
- New Zealand Environmental Protection Authority New Zealand HSNO Chemical Classifications,
 6.7A Known or presumed human carcinogens. This equates to a HIGH level of concern in the QCAT methodology.
- Government of Japan GHS Classifications Carcinogenicity Category 1B
- US Environmental Protection Agency Risk Management Actions & TSCA Work Plans, Probable human carcinogen TSCA Criteria met. This equates to a HIGH level of concern in the QCAT methodology.
- European Commission Classification, Labelling and Packaging Regulation (CLP) Classification and Labelling Inventory CMRs Carcinogen Category 2 Suspected human carcinogen. This equates to a HIGH level of concern in the QCAT methodology

Moderate level of concern:

- European Commission Substances with EU Risk & Safety Phrases (Commission Directive 67-548-EEC) R40: Limited evidence of a carcinogenic effect. This equates to a MODERATE level of concern in the QCAT methodology.
- European Commission Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Annex 6 Table 3-1 GHS Hazard code criteria H351 Suspected of causing cancer. This equates to a MODERATE level of concern in the QCAT methodology.
- MAK Commission of Germany (Deutsche Forschungsgemeinschaft) List of Substances with MAK & BAT Values & Categories Carcinogen Group 3B Evidence of carcinogenic effects but not sufficient for classification. This equates to a MODERATE level of concern in the QCAT methodology.

Mutagenicity and Genotoxicity (M) Hazard Level (H, M, L or DG): M

Research Summary: Data on mutagenicity and genotoxicity was limited. The HSDB had numerous references to studies (more than 10) that reported no evidence of mutagenicity or genotoxicity of PERC in mice. Two HSDB studies that did indicate genotoxicity are summarized below. Based upon this information, a **MODERATE** level of concern was assigned for mutagenicity and genotoxicity.

HSDB:

Moderate level of concern:

- HSDB: /GENOTOXICITY/ The clastogenicity of **tetrachloroethylene** (tetra) was detected by means of the micronucleus assay using hepatocytes and reticulocytes from ddY male mice, to understand its effects in upon hepatocellular carcinomas in mice. The frequency of micronucleated hepatocytes of mice that received a single injection of tetra after partial hepatectomy increased to levels that were significantly higher than those of controls treated with solvent. However, the micronucleus assay using peripheral blood reticulocytes from ddY male mice, revealed that tetra did not induce to a statistically significant increase in micronucleus frequency. These results suggested that tetra metabolites have a clastogenic effect in vivo upon mouse liver but not upon bone marrow cells.

 [Murakami k, Horikawa K; Chemosphere 31 (7): 3733-9 (1995)] **PEER REVIEWED***
- /GENOTOXICITY/ Induction of DNA damage in the liver and kidney of male CD1 mice was studied by means of the alkaline Comet assay after oral administration of **tetrachloroethylene** at the doses of 1000 and 2000 mg/kg/day. A statistically significant dose-related increase in tail intensity was established in hepatocytes, indicating that **tetrachloroethylene** induced DNA damage in the liver. No effect on DNA damage was observed in the kidney. The results are in agreement with carcinogenicity data in mice, in which **tetrachloroethylene** induced tumors in the liver but not in the kidney, and support that a genotoxic mode of action might be involved in liver carcinogenicity in mice.

[Cederberg H et al; Mutagenesis 25 (2): 133-8 (2010)] **PEER REVIEWED** PubMed Abstract

Reproductive Toxicity (R) Hazard Level (H, M, L or DG): M

Research Summary: Data for reproductive toxicity was limited. An assessment by the Japanese METI/MOE assigned a classification of Category 2 to tetrachloroethylene. This equates to a **MODERATE** level of concern using the QCAT criteria and was used to assign the same level of reproductive concern for tetrachloroethylene.

References:

Japan/METI/MOE:

• GS Classifications, Toxic to reproduction, Category 2.

Development Tox. including Developmental Neurotoxicity (D) Hazard Level (H, M, L or DG): H

Research Summary: Data on developmental toxicity is limited. Tetrachloroethylene is identified by one authoritative source, Grandjean and Landrigan, as a neurodevelopmental toxicant. Based upon this limited information, tetrachloroethylene was assigned a **HIGH** level of concern.

References:

<u>Grandjean & Landrigan</u>, Neurobehavioral effects of developmental toxicity, Lancet Neurol, 2014, 13:330-38.

• Identified as a developmental neurotoxicants.

Endocrine Disruption (E) Hazard Level (H, M, L or DG): M

Research Summary: Two sources of data were identified. One, the European Commission identified a moderate level of concern. The second, TEDX, identified the chemical as a potential endocrine disruptor and added it to the list of chemicals for more review. As the TEDX is more of a screening list, greater emphasis was placed upon the authoritative EC determination; therefore, a **MODERATE** level of concern was assigned to tetrachloroethylene for endocrine disruption.

References:

European Commission:

• EU Community Strategy for Endocrine Disrupters - Priority List Category 2 - In vitro evidence of biological activity related to endocrine disruption. This equates to a MODERATE level of concern using the QCAT criteria.

The Endocrine Disruption Exchange (TEDX):

• *TEDX List of Potential Endocrine Disruptors* Potential Endocrine Disruptor. This equates to a HIGH level of concern using the QCAT criteria.

Human Health Effects – Group II

Acute Mammalian Toxicity (AT) Hazard Level (VH, H, M, L or DG):

Research Summary: Based upon data identified in HSDB, numerous inhalation rat and mouse data and one oral rat study identify a moderate level of concern for acute mammalian toxicity using QCAT

chemical ranking criteria. One study reported in both HSDB and RTECs identified an oral rat LD₅₀ of 2,629 mg/kg which equates to a low level of concern using QCAT chemical ranking criteria. As there were numerous inhalation and an additional oral rat study that identified a moderate level of concern and only one study that identified a low level of concern, PERC was assigned a **MODERATE** level of concern for acute mammalian toxicity.

HSDB:

Moderate level of concern:

• LD₅₀ Rat oral 320 mg/kg bw

[European Commission, ESIS; IUCLID Dataset, Tetrachloroethylene (127-18-4) p. 83 (2000 CD-ROM edition). Available from, as of September 23, 2010: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

• LC₅₀ Rat inhalation 4,100 ppm/6 hr

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at:

http://monographs.iarc.fr/ENG/Classification/index.php p. V63 191 (1995)] **PEER REVIEWED**

• LC₅₀ Rat inhalation 5,000 ppm/8 hr

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at:

http://monographs.iarc.fr/ENG/Classification/index.php
p. V63 191 (1995)] **PEER

REVIEWED**

• LC₅₀ Mouse inhalation 5,200 ppm/4 hr

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at:

http://monographs.iarc.fr/ENG/Classification/index.php p. V63 191 (1995)] **PEER REVIEWED**

• LC₅₀ Mouse inhalation 2,978 ppm/6 hr

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at:

http://monographs.iarc.fr/ENG/Classification/index.php p. V63 191 (1995)] **PEER REVIEWED**

• LC₅₀ Rat inhalation 4,000 ppm/4hr

[American Conference of Governmental Industrial Hygienists. Documentation of the TLV's and BEI's with Other World Wide Occupational Exposure Values. CD-ROM Cincinnati, OH 45240-4148 2010.] **PEER REVIEWED**

• LC₅₀ Rat Inhalation 2,445 ppm/ 4 hr

[National Industrial Chemicals Notification and Assessment Scheme; Tetrachloroethylene (127-18-4) Assessment Report No. 15 p. 46 (June 2001). Available from as of September 29, 2010:http://www.nicnas.gov.au/Publications/CAR/PEC.asp **PEER REVIEWED**

Low level of concern

• LD₅₀ Rat oral 2,629 mg/kg

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[Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2857] **PEER REVIEWED**
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RTECS:

Low level of concern:

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LD<sub>50</sub> - Lethal dose, 50 percent kill Oral Rodent - rat 2,629 mg/kg
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Environmental Health Effects

Acute Aquatic (AA) Toxicity Hazard Level: (VH, H, M, L or DG): VH

Research Summary: Based upon data identified in Pharos, two sources identified a very high level of concern for acute aquatic toxicity using QCAT chemical ranking criteria. New Zealand had identified the chemical as very ecotoxic in the aquatic environment (9.1A) and Japan NITE as a category 1 aquatic environment toxicant. Pharos also identified a third source. The European Union assigned PERC a risk phrase of R51, toxic to aquatic organisms. This equates to a high level of concern using QCAT chemical ranking criteria. As two of the three sources indicated PERC is very highly toxic to the aquatic environment PERC was assigned a **VERY HIGH** level of concern for acute aquatic toxicity.

References:

Pharos:

Very high level of concern:

- New Zealand GHS 9.1A (algal) Very ecotoxic in the aquatic environment
- Japan GHS Hazardous to the aquatic environment (acute) Category 1

High level of concern:

• EU – Risk Phrases: R51, Toxic to aquatic organisms

Environmental Fate

Persistence (P) Hazard Level: (VH, H, M, L, VL or DG): VH

Research Summary: PERC is identified by Environment Canada as persistent which equates to a high level of concern using the QCAT chemical ranking criteria. Data within the HSDB suggests that PERC will degrade in air and water with a half-life of 96 days and 9 months, respectively. Both of these values equate to a very high level of concern using QCAT chemical ranking criteria. Lastly, EPA's PBT Profiler assigns a half-life in water and air, the two media to which 93% of PERC is expected to be found, of 60 and 96 days for a high and very high level of concern, respectively. As several data sources indicate a very high level of concern, PERC is assigned a <u>VERY HIGH</u> for persistence.

References:

Pharos:

• Environment Canada-Domestic Substances List: Persistent

HSDB (emphasis added):

• If released to air, a vapor pressure of 18.5 mm Hg at 25 deg C indicates **tetrachloroethylene** will exist solely as a vapor in the atmosphere. Vapor-phase **tetrachloroethylene** will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; **the half-life for this reaction in air is estimated to be 96 days**. Hydrolysis is not expected to be an important environmental fate process based on a **hydrolysis half-life of 9 months**. (SRC)

PBT Profiler:

• EPA's PBT Profiler Provided the following results for PERC:

| Media | Half-life (days) | % in each medium |
|------------|------------------|------------------|
| - Water | 60 | 47 |
| - Soil | 120 | 7 |
| - Sediment | 540 | 0 |
| - Air | 96 | 46 |

Bioaccumulation (B) Potential Hazard Level: (vH, H, M, L, vL or DG): L

Research Summary: Three sources identified that PERC had either a very low or low bioaccumulation potential. The HSDB identified BCF values ranging between 26 and 115 which equates to a very low to low level of concern, respectively, using QCAT chemical ranking criteria. The PBT Profiler assigned a BCF of 81 which also equates to a very low level of concern. The Canadian DSL indicated PERC was not bioaccumulative. Based upon these results, PERC was assigned a **LOW** level of concern for bioaccumulation.

References:

HSDB (emphasis added):

• ... Measured <u>BCF values of 26-115</u> in fish indicate that bioconcentration in aquatic organisms is low to high. (SRC)

PBT Profiler:

• EPA's PBT Profiler indicated a BCF = 81 for PERC.

Canadian DSL listing:

Not bioaccumulative.

Appendix A:

AA = Acute Aquatic Toxicity

AT = Acute Mammalian Toxicity

B = Bioaccumulation C = Carcinogenicity

CA = Chronic Aquatic Toxicity

D = Developmental Toxicity (incl. Developmental Neurotoxicity)

E = Endocrine Activity

Eo = Other Ecotoxicity studies

F = Flammability

HH1 = Human Health Group 1 (C, M, R, D, E)

HH2 = Human Health Group 2 (AT)

IrE = Irritation-Eye
IrS = Irritation-Skin

M = Mutagenicity & Genotoxicity

N = Neurotoxicity P = Persistence

R = Reproductive Toxicity

Rd = Repeat dose Rx = Reactivity Sd = Single dose

SnR = Sensitization-Respiratory

SnS = Sensitization-Skin

ST = Systemic Toxicity & Organ Effects (incl. Immunotoxicity)

Appendix 8: Chemical Ranking Criteria - updated June 7, 2016

Please note:

These appendices are updated frequently and may be outdated. Updated versions are available on the QCAT website at www.ecy.wa.gov/GreenChemistry/QCAT.html. Go to the website and check the dates to make sure you are using the most current version.

| | Human Health: Carcinogenicity | | | |
|------|--|---|---|--|
| | High (H) | Low (L) | | |
| Step | I Sources | | | |
| # | Priority Sources | | | |
| 1 | US NIH - Report on Carcinogens Known to be a human Carcinogen Known to be Human Carcinogen (respirable size - occupational setting) Reasonably Anticipated to be Human Carcinogen Reasonably Anticipated to be Human Carcinogen (respirable size - occupational setting) | | | |
| 2 | CA EPA - Prop 65 Carcinogen Carcinogen (form-specific or based on limited exposure pathways) | | | |
| 3 | EU - SVHC Authorisation List Carcinogenic - Banned unless Authorised Carcinogenic - Candidate list Carcinogenic - Prioritized for listing | | | |
| 4 | US CDC - Occupational Carcinogens Occupational Carcinogen | | | |
| 5 | IARC Group 1 - Agent is Carcinogenic to humans Group 1 - Agent is carcinogenic to humans - inhaled from occupational sources Group 2a - Agent is probably Carcinogenic to humans Group 2A - Agent is probably carcinogenic to humans - inhaled from occupational sources | IARC Group 2b - Possibly carcinogenic to humans Group 2b - Possibly carcinogenic to humans - inhaled from occupational sources Group 3 - Agent is not classifiable as to its carcinogenicity to humans | IARC Group 4 - Agent is probably not carcinogenic to humans | |
| 6 | US EPA - IRIS Carcinogens (1986) Group A - Human Carcinogen (1986) Group B1 - Probable human Carcinogen (1986) Group B2 - Probable human Carcinogen (1996) Known/likely human Carcinogen (1999) Carcinogenic to humans (1999) Likely to be Carcinogenic to humans (2005) Carcinogenic to humans (2005) Likely to be Carcinogenic to humans | US EPA - IRIS Carcinogens (1986) Group C - Possible human Carcinogen (1986) Group D - Not classifiable as to human carcinogenicity (1999) Suggestive evidence of carcinogenicity (2005) Suggestive evidence of Carcinogenic potential | US EPA - IRIS Carcinogens (1986) Group E - Evidence of non- carcinogenicity for humans (1996) Not likely to be carcinogenic to humans (1999) Not likely to be Carcinogenic to humans (2005) Not likely to be Carcinogenic to humans | |
| 7 | EU - Annex VI CMRs Carcinogen Category 1A - Known human Carcinogen based on human evidence Carcinogen Category 1B - Presumed Carcinogen based on animal evidence | EU - Annex VI CMRs Carcinogen Category 2 - Suspected human Carcinogen | | |
| 8 | EU - GHS (H-Statements) H350 - May cause cancer H350i - May cause cancer by inhalation | EU - GHS (H-Statements) H351 - Suspected of causing cancer | | |

| | Human Health: Carcinogenicity | | | | |
|------|---|---|--|--|--|
| | High (H) Moderate (M) Low (L) | | | | |
| Step | p I Sources | | | | |
| # | Priority Sources | | | | |
| 9 | EU - REACH Annex XVII CMRs Carcinogen Category 1 - Substances known to be Carcinogenic to man Carcinogen Category 2 - Substances which should be regarded as if they are Carcinogenic to man | EU - REACH Annex XVII CMRs Carcinogen Category 3 - Possibly Carcinogenic to humans (listed as Carc. Cat. 3) | | | |
| 10 | EU - R-phrases R45 - May cause cancer R49 - May cause cancer by inhalation | EU - R-phrases R40 - Limited Evidence of Carcinogenic Effects | | | |
| 11 | MAK Carcinogen Group 1 - Substances that cause cancer in man Carcinogen Group 2 - Considered to be carcinogenic for man | MAK Carcinogen Group 3A - Evidence of carcinogenic effects but not sufficient to establish MAK/BAT value Carcinogen Group 3B - Evidence of carcinogenic effects but not sufficient for classification Carcinogen Group 4 - Non-genotoxic carcinogen with low risk under MAK/BAT levels Carcinogen Group 5 - Genotoxic carcinogen with very slight risk under MAK/BAT levels | | | |
| # | Secondary Sources | | | | |
| 12 | Japan – GHS Carcinogenicity - Category 1, 1A or 1B | Japan – GHS Carcinogenicity - Category 2 | Japan – GHS Not classified (sufficient information; chemical is not problematic) | | |
| 13 | Korea – GHS Carcinogenicity - Category 1, 1A or 1B [H350 - May cause cancer] | Korea – GHS Carcinogenicity - Category 2 [H351 - Suspected of causing cancer] | | | |
| 14 | New Zealand – GHS 6.7A - Known or presumed human carcinogens | New Zealand - GHS 6.7B - Suspected human carcinogens | | | |
| Step | tep II Sources | | | | |
| 15 | ISSCAN Value Ranking = 3, Carcinogenic | ISSCAN Value Ranking = 2, Undetermined or equivocal | ISSCAN Value Ranking = 1, Non-carcinogenic | | |
| 16 | ECHA C&L Inventory Carcinogen Category 1, 1A or 1B - Known or presumed human carcinogen | ECHA C&L Inventory Carcinogen Category 2 - Suspected human carcinogens | | | |
| 17 | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Strong evidence of carcinogenicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR) etc. Indication of carcinogenicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR) etc. Indication of no carcinogenicity | | |

| | Human Health: Mutagenicity/Genotoxicity | | | |
|-----|---|---|--|--|
| | High (H) | Moderate (M) | Low (L) | |
| Ste | o I Sources | | | |
| # | Priority Sources | | | |
| 3 | EU - SVHC Authorisation List Mutagenic - Banned unless Authorised Mutagenic - Candidate list Mutagenic - Prioritized for listing | | | |
| 7 | EU - Annex VI CMRs Mutagen - Category 1A Mutagen - Category 1B | EU - Annex VI CMRs Mutagen - Category 2 | | |
| 8 | EU - GHS (H-Statements) H340 - May cause genetic defects | EU - GHS (H-Statements) H341 - Suspected of causing genetic defects | | |
| 9 | EU - REACH Annex XVII CMRs Mutagen Category 1 - Substances known to be Mutagenic to man Mutagen Category 2 - Substances which should be regarded as if they are Mutagenic to man | EU - REACH Annex XVII CMRs Category 3 - Substances which cause concern for man owing to possible mutagenic effects | | |
| 10 | EU - R-phrases R46 - May cause heritable genetic damage | EU - R-phrases R68 - May cause irreversible effects | | |
| 11 | MAK Germ Cell Mutagen 1 Germ Cell Mutagen 2 Germ Cell Mutagen 3a | MAK Germ Cell Mutagen 3b Germ Cell Mutagen 5 | | |
| # | Secondary Sources | | | |
| 12 | Japan - GHS Germ cell mutagenicity - Category 1, 1A or 1B | Japan - GHS Germ cell mutagenicity - Category 2 | Japan – GHS Not classified (sufficient information; chemical is not problematic) | |
| 13 | Korea - GHS Germ cell mutagenicity - Category 1, 1A or 1B [H340 - May cause genetic defects] | Korea - GHS Germ cell mutagenicity - Category 2 [H341 - Suspected of causing genetic defects] | | |
| 14 | New Zealand - GHS 6.6A - Known or presumed human mutagens | New Zealand - GHS 6.6B - Suspected human mutagens | | |
| Ste | o II Sources | | | |
| 15 | ISSCAN SAL Value: Ranking = 3, Mutagenic | ISSCAN SAL Value: Ranking = 2, Undetermined or equivocal | ISSCAN SAL Value: Ranking = 1, Non-mutagenic | |
| 16 | ECHA C&L Inventory Category 1, 1A, or 1B: Known/Presumed to induce heritable mutations | ECHA C&L Inventory Category 2: Suspected to induce heritable mutations | | |
| 17 | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Strong evidence of mutagenicity/genotoxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Indication of mutagenicity/genotoxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Adequate data available and negative studies | |

| | Human Health: Reproductive Toxicity | | | | | |
|-----------|---|---|---|--|--|--|
| | High (H) | Moderate (M) | Low (L) | | | |
| Ste | ep I Sources | | | | | |
| # | Priority Sources | | | | | |
| <u>2</u> | CA EPA - Prop 65 Developmental Toxicity - Female (may include additional qualifications) Developmental Toxicity - Male (may include additional qualifications) | | | | | |
| <u>3</u> | EU - SVHC Authorisation List ¹⁴ Toxic to reproduction - Banned unless Authorised Toxic to reproduction - Candidate list Toxic to reproduction - Prioritized for listing | | | | | |
| 7 | EU - Annex VI CMRs Reproductive Toxicity - Category 1A Reproductive Toxicity - Category 1B | EU - Annex VI CMRs Reproductive Toxicity - Category 2 | | | | |
| <u>8</u> | EU - GHS (H-Statements) H360 - May damage fertility or the unborn child H360F - May damage fertility H360FD - May damage fertility. May damage the unborn child H360Fd - May damage fertility. Suspected of damaging the unborn child | EU - GHS (H-Statements) H360Df - May damage fertility. Suspected of damaging the unborn child H361 - Suspected of damaging fertility or the unborn child H361f - Suspected of damaging fertility H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child | | | | |
| 9 | EU - REACH Annex XVII CMRs Toxic to Reproduction Category 1 - Substances known to impair fertility or cause Developmental Toxicity in humans Toxic to Reproduction Category 2 - Substances which should be regarded as if they impair fertility or cause Developmental Toxicity in humans | EU - REACH Annex XVII CMRs Toxic to Reproduction Category 3: Suspected to impair fertility or cause Developmental Toxicity in humans | | | | |
| <u>10</u> | EU - R-phrases R60 - May impair fertility | EU - R-phrases R62 - Possible risk of impaired fertility | | | | |
| 18 | US NIH - Reproductive & Developmental Monographs Clear Evidence of Adverse Effects - Reproductive Toxicity Some Evidence of Adverse Effects - Reproductive Toxicity Limited Evidence of Adverse Effects - Reproductive Toxicity | US NIH - Reproductive & Developmental Monographs Limited Evidence of no Adverse Effects - Reproductive Toxicity Some Evidence of no Adverse Effects - Reproductive Toxicity Insufficient Evidence for a Conclusion - Reproductive Toxicity | US NIH - Reproductive & Developmental Monographs Clear Evidence of no Adverse Effects - Reproductive Toxicity | | | |
| # | Secondary Sources | | | | | |
| <u>12</u> | Japan - GHS Toxic to reproduction - Category 1, 1A or 1B | Japan - GHS Toxic to reproduction - Category 2 | Japan – GHS Not classified (sufficient information; chemical is not problematic) | | | |
| <u>13</u> | Korea - GHS Reproductive toxicity - Category 1, 1A or 1B: [H360 - May damage fertility or the unborn child] | Korea - GHS Reproductive toxicity - Category 2 [H361 - Suspected of damaging fertility or the unborn child] | | | | |

¹⁴ ECHA listings and EU CMRs include both reproductive and developmental effects in one grouping under a broad definition of "Reproductive toxicity". For the purposes of QCAT, the distinction between whether these are listings are actually due to reproductive or developmental effects is left for a more detailed assessment such as the GS®. The QCAT will assume that all of the effects are grouped here.

| | Human Health: Reproductive Toxicity | | | |
|-----------|---|--|--|--|
| | High (H) | Moderate (M) | Low (L) | |
| Step | I Sources | | | |
| # | Secondary Sources | | | |
| <u>14</u> | New Zealand - GHS 6.8A - Known or presumed human reproductive or developmental toxicants 6.8C - Produce toxic human reproductive or developmental effects on or via lactation | New Zealand - GHS 6.8B - Suspected human reproductive or developmental toxicants | | |
| Step | Il Sources | | | |
| 16 | ECHA C&L Inventory Use classification (e.g., Category 1) or H-Statement as shown in Step I above | Use classification (e.g., Category 2) or H-Statement as shown in Step I above | | |
| 17 | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Strong evidence of reproductive toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Indication of reproductive toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Indication of no reproductive toxicity | |
| 19 | $\label{eq:continuous_problem} \begin{split} \textbf{EPA Characterization Criteria:} \\ \textbf{LOAEL, TD}_{lo} \text{ or TC}_{lo} Values \\ \textbf{Oral} &< 50 \text{ mg/kg-bw/d} \\ \textbf{Dermal} &< 100 \text{ mg/kg-bw/d} \\ \textbf{Inhalation (vapor)} &< 1.0 \text{ mg/L/d} \\ \textbf{Inhalation (dust/mist/fume)} &< 0.1 \text{ mg/L/d} \\ \textbf{Inhalation (gas)} &< 50 \text{ ppm/d} \end{split}$ | $\label{eq:continuous_problem} \begin{split} \textbf{EPA Characterization Criteria:} \\ \textbf{LOAEL, TD}_{1o} \text{ or TC}_{1o} \text{Values} \\ \textbf{Oral} & \geq 50 \text{ but} < 250 \text{ mg/kg-bw/d} \\ \textbf{Dermal} & \geq 100 \text{ but} < 500 \text{ mg/kg-bw/d} \\ \textbf{Inhalation (vapor)} & \geq 1.0 \text{ but} < 2.5 \text{ mg/L/d} \\ \textbf{Inhalation (dust/mist/fume)} & \geq 0.1 \text{ but} < 0.5 \text{ mg/L/d} \\ \textbf{Inhalation (gas)} & \geq 50 \text{ but} < 250 \text{ ppm/d} \end{split}$ | $\label{eq:continuous_problem} \begin{split} \textbf{EPA Characterization Criteria:} \\ \textbf{LOAEL, TD}_{lo} \text{ or TC}_{lo} Values \\ \textbf{Oral} &\geq 250 \text{ mg/kg-bw/d} \\ \textbf{Dermal} &\geq 500 \text{ mg/kg-bw/d} \\ \textbf{Inhalation (vapor)} &\geq 2.5 \text{ mg/L/d} \\ \textbf{Inhalation (dust/mist/fume)} &\geq 0.5 \text{ mg/L/d} \\ \textbf{Inhalation (gas)} &\geq 250 \text{ ppm/d} \end{split}$ | |

| | Human Health: Developmental (including Developmental Neurotoxicity) | | | |
|-----|---|--|---------|--|
| | High (H) | Moderate (M) | Low (L) | |
| Ste | p I Sources | | | |
| # | Priority Sources | | | |
| 2 | CA EPA - Prop 65 Developmental toxicity Developmental (form-specific or based on limited exposure pathways) | | | |
| 3 | EU - SVHC Authorisation List Toxic to reproduction - Banned unless Authorised (if identified due to developmental toxicity) Toxic to reproduction - Candidate list (if identified due to developmental toxicity) Toxic to reproduction - Prioritized for listing (if identified due to developmental toxicity) | | | |
| 8 | EU - GHS (H-Statements) H360D - May damage the unborn child H360Df - May damage the unborn child H360FD - May damage the unborn child H362 - May cause harm to breast-fed children | EU - GHS (H-Statements) H360Fd - May damage fertility. Suspected of damaging the unborn child. H361 - Suspected of damaging fertility or the unborn child H361d - Suspected of damaging the unborn child H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child. | | |

| | Human Health: Developmental (including Developmental Neurotoxicity) | | | | | |
|-----|---|---|--|--|--|--|
| | High (H) | Moderate (M) | Low (L) | | | |
| Ste | ep I Sources | | | | | |
| # | Priority Sources | | | | | |
| 10 | EU - R-phrases R61 - May cause harm to the unborn child R64 - May cause harm to breastfed babies | EU - R-phrases R63 - Possible risk of harm to the unborn child | | | | |
| 11 | MAK Pregnancy Risk Group A Pregnancy Risk Group B | MAK Pregnancy Risk Group C Pregnancy Risk Group D | | | | |
| 18 | US NIH - Reproductive & Developmental Monographs Clear Evidence of Adverse Effects - Developmental Toxicity Some Evidence of Adverse Effects - Developmental Toxicity Limited Evidence of Adverse Effects- Developmental Toxicity | US NIH - Reproductive & Developmental Monographs Some Evidence of no Adverse Effects - Developmental Toxicity Limited Evidence of no Adverse Effects - Developmental Toxicity Insufficient Evidence for a Conclusion - Developmental Toxicity | US NIH - Reproductive & Developmental Monographs Clear Evidence of no Adverse Effects - Developmental Toxicity | | | |
| # | Secondary Sources | | | | | |
| 12 | Japan - GHS Category 1, 1A or 1B: Known/Presumed to induce developmental toxicity | Japan - GHS Category 2: Suspected to induce developmental toxicity | Japan – GHS Not classified (sufficient information; chemical is not problematic) | | | |
| 13 | Korea - GHS Category 1, 1A or 1B: Known/Presumed to induce developmental toxicity | Korea – GHS Category 2: Suspected to induce developmental toxicity H362: May cause harm to breast-fed children | | | | |
| 14 | New Zealand - GHS 6.8A or 6.8C - Indication of developmental toxicity | New Zealand - GHS 6.8B - Indication of developmental toxicity | | | | |
| 19 | Boyes – Neurotoxicants Developmental Neurotoxicity | | | | | |
| 20 | G&L - Neurotoxic Chemicals Developmental Neurotoxicant Developmental Neurotoxicant (2014) | | | | | |
| Ste | p II Sources | | | | | |
| 16 | ECHA C&L Inventory Use classification (e.g., Category 1) or H-Statement as shown in Step I above | ECHA C&L Inventory Use classification (e.g., Category 1) or H-Statement as shown in Step I above | | | | |
| 17 | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Strong evidence of developmental toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Indication of developmental toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Indication of no developmental toxicity | | | |

| | Human Health: Endocrine Activity | | | |
|-----|--|---|---|--|
| | High (H) | Moderate (M) | Low (L) | |
| Ste | p I Sources | | | |
| # | Priority Sources | | | |
| 3 | EU - SVHC Authorisation List Equivalent Concern - Banned unless Authorised Equivalent Concern - Candidate list Equivalent Concern - Prioritized for listing | | | |
| # | Secondary Sources | | | |
| 21 | EU - Priority Endocrine Disrupters Category 1 - In vivo evidence of Endocrine Disruption Activity Category 2 - In vitro evidence of biological activity related to Endocrine Disruption | EU - Priority Endocrine Disrupters Category 3b (Substances with no or insufficient data gathered) | EU - Priority Endocrine Disrupters Category 3a (ED Studies available but no indication of ED effects) | |
| 22 | OSPAR - Priority PBTs & EDs & equivalent concern Endocrine Disruptor - Chemical for Priority Action Endocrine Disruptor - Substance of Possible Concern | | | |
| 23 | ChemSec - SIN List Endocrine Disruption | | | |
| 24 | TEDX - Potential Endocrine Disruptors Potential Endocrine Disruptor | | | |
| Ste | p II Sources | | | |
| 17 | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Evidence of endocrine activity & related human health effect | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Some evidence of endocrine activity and effects | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Adequate data available-evidence of no endocrine activity | |

| | Human Health: Acute Mammalian Toxicity | | | |
|------|---|---|--|--|
| | Very High (v) | High (H) | Moderate (M) | Low (L) |
| Step | I Sources | | | |
| # | Priority Sources | | | |
| 8 | EU - GHS (H-Statements) H300 - Fatal if swallowed H310 - Fatal in contact with skin H330 - Fatal if inhaled | EU - GHS (H-Statements) H301 - Toxic if swallowed H311 - Toxic in contact with skin H331 - Toxic if inhaled | EU - GHS (H-Statements) H302 - Harmful if swallowed H312 - Harmful in contact with skin H332 - Harmful if inhaled | EU - GHS (H-Statements) H303 - May be harmful if swallowed H313 - May be harmful in contact with skin H333 - May be harmful if inhaled |
| 10 | EU - R-phrases R26 - Very Toxic by Inhalation R27 - Very Toxic in Contact with Skin R28 - Very Toxic if Swallowed | EU - R-phrases R23 - Toxic by Inhalation (gas, vapour, dust/mist) R24 - Toxic in Contact with Skin R25 - Toxic if Swallowed | EU - R-phrases R20 - Harmful by Inhalation (gas or vapor or dust/mist) R21 - Harmful in Contact with Skin R22 - Harmful if Swallowed | |
| 26 | US EPA - EPCRA Extremely Hazardous Substances Extremely Hazardous Substances | | | |

| | | Human Health: Acute | Mammalian Toxicity | | | | | |
|------|---|--|--|--|--|--|--|--|
| | Very High (v) | High (H) | Moderate (M) | Low (L) | | | | |
| Step | I Sources | | | | | | | |
| # | Secondary Sources | | | | | | | |
| 12 | Japan - GHS Acute toxicity (dermal) - Category 1 Acute toxicity (inhalation: dust, mist) - Category 1 Acute toxicity (inhalation: gas) - Category 1 Acute toxicity (inhalation: vapor) - Category 1 Acute toxicity (oral) - Category 1 Acute toxicity (dermal) - Category 2 Acute toxicity (inhalation: dust, mist) - Category 2 Acute toxicity (inhalation: gas) - Category 2 Acute toxicity (inhalation: vapor) - Category 2 Acute toxicity (oral) - Category 2 | Japan - GHS Acute toxicity (dermal) - Category 3 Acute toxicity (inhalation: dust, mist) - Category 3 Acute toxicity (inhalation: gas) - Category 3 Acute toxicity (inhalation: vapor) - Category 3 Acute toxicity (oral) - Category 3 | Japan - GHS Acute toxicity (dermal) - Category 4 Acute toxicity (inhalation: dust, mist) - Category 4 Acute toxicity (inhalation: gas) - Category 4 Acute toxicity (inhalation: vapor) - Category 4 Acute toxicity (oral) - Category 4 | Japan - GHS Acute toxicity (dermal) - Category 5 Acute toxicity (inhalation: dust, mist) - Category 5 Acute toxicity (inhalation: gas) - Category 5 Acute toxicity (inhalation: vapor) - Category 5 Acute toxicity (oral) - Category 5 | | | | |
| 13 | Korea - GHS Acute toxicity (dermal) - Category 1 [H310 - Fatal in contact with skin] Acute toxicity (inhalation) - Category 1 [H330 - Fatal if inhaled] Acute toxicity (oral) - Category 1 [H300 - Fatal if swallowed] Acute toxicity (dermal) - Category 2 [H310 - Fatal in contact with skin] Acute toxicity (inhalation) - Category 2 [H330 - Fatal if inhaled] Acute toxicity (oral) - Category 2 [H300 - Fatal if swallowed] | Korea - GHS Acute toxicity (dermal) - Category 3 [H311 - Toxic in contact with skin] Acute toxicity (inhalation) - Category 3 [H331 - Toxic if inhaled] Acute toxicity (oral) - Category 3 [H301 - Toxic if swallowed] | Korea - GHS Acute toxicity (dermal) - Category 4 [H312 - Harmful in contact with skin] Acute toxicity (inhalation) - Category 4 [H332 - Harmful if inhaled] Acute toxicity (oral) - Category 4 [H302 - Harmful if swallowed] | | | | | |
| 14 | New Zealand - GHS 6.1A (dermal) - Acutely toxic 6.1A (inhalation) - Acutely toxic 6.1A (oral) - Acutely toxic 6.1B (dermal) - Acutely toxic 6.1B (inhalation) - Acutely toxic 6.1B (oral) - Acutely toxic | New Zealand - GHS 6.1C (dermal) - Acutely toxic 6.1C (inhalation) - Acutely toxic 6.1C (oral) - Acutely toxic | New Zealand - GHS 6.1D (dermal) - Acutely toxic 6.1D (inhalation) - Acutely toxic 6.1D (oral) - Acutely toxic | New Zealand - GHS 6.1E (dermal) - Acutely toxic 6.1E (inhalation) - Acutely toxic 6.1E (oral) - Acutely toxic | | | | |
| 27 | Québec CSST - WHMIS 1998 Class D1A - Very toxic material causing immediate and serious toxic effects | Québec CSST - WHMIS 1998 Class D1B - Toxic material causing immediate and serious toxic effects | | | | | | |
| Step | Il Sources | | | | | | | |
| 16 | ECHA C&L Inventory Use classification (e.g., Category 1 or 2) or H- Statement as shown in Step I above | ECHA C&L Inventory Use classification (e.g., Category 3) or H- Statement as shown in Step I above | Use classification (e.g., Category 4) or H- Statement as shown in Step I above | ECHA C&L Inventory Use classification (e.g., Category 5) or H- Statement as shown in Step I above | | | | |
| 17 | N/A | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Strong evidence of acute mammalian toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), etc. Indication of acute mammalian toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB UNEP SIDS, OSHA, Danish Q(SAR), etc Indication of no acute mammalian toxicity | | | | |

| | | Human Health: Acute | Human Health: Acute Mammalian Toxicity | | | | | | | | |
|------|--|---|---|--|--|--|--|--|--|--|--|
| | Very High (v) | High (H) | Low (L) | | | | | | | | |
| Step | II Sources | | | | | | | | | | |
| | Technical Criteria | Technical Criteria | Technical Criteria | Technical Criteria | | | | | | | |
| | Oral $LD_{50} \le 50$ mg/kg bw | Oral LD ₅₀ $>$ 50 but \leq 300 mg/kg bw | Oral LD ₅₀ > 300 but \leq 2,000 mg/kg bw | Oral $LD_{50} > 2,000 \text{ mg/kg bw}$ | | | | | | | |
| 19 | Dermal LD ₅₀ \leq 200 mg/kg bw | Dermal LD ₅₀ $>$ 200 but \le 1,000 mg/kg bw | Dermal LD ₅₀ > 1,000 but \leq 2,000 mg/kg bw | Dermal LD ₅₀ $> 2,000$ mg/kg bw | | | | | | | |
| 19 | Inhalation (g) $LC_{50} \le 500$ ppm | Inhalation (g) LC ₅₀ $>$ 500 but \leq 2,500 ppm | Inhalation (g) LC ₅₀ > 2,500 but \leq 20,000 ppm | Inhalation (g) LC ₅₀ $>$ 20,000 ppm | | | | | | | |
| | Inhalation (v) $LC_{50} \le 2.0 \text{ mg/l}$ | Inhalation (v) LC ₅₀ \geq 2.0 but \leq 10.0 mg/l | Inhalation (v) LC ₅₀ > 10.0 but \leq 20.0 mg/l | Inhalation (v) LC ₅₀ $>$ 20.0 mg/l | | | | | | | |
| | Inhalation (dust, mist) $LC_{50} \le 0.5$ mg/l | Inhalation (dm) $LC_{50} > 0.5$ but ≤ 1.0 mg/l | Inhalation (dm) LC ₅₀ > 1.0 but \leq 5.0 mg/l | Inhalation (dm) $LC_{50} > 5.0 \text{ mg/l}$ | | | | | | | |

| | | Environmental Health: | | |
|------|---|---|---|---|
| | Very High (v) | High (H) | Moderate (M) | Low (L) |
| Step | I Sources | | | |
| # | Priority Sources | | | |
| 8 | EU - GHS (H-Statements) H400 - Very toxic to aquatic life | | | |
| 10 | EU - R-phrases R50 - Very Toxic to Aquatic Organisms | EU - R-phrases R51 - Toxic to Aquatic Organisms R52 - Harmful to Aquatic Organisms R51/53 - Toxic to Aquatic Organisms, May cause long-term adverse effects in the aquatic environment | EU - R-phrases R53 - May cause long-term adverse effects in the aquatic environment R52/53 - Harmful to Aquatic Organisms, May cause long-term adverse effects in the aquatic environment | |
| # | Secondary Sources | | | |
| 12 | Japan – GHS Hazardous to the aquatic environment (acute) - Category 1 | Japan – GHS Hazardous to the aquatic environment (acute) - Category 2 | Japan – GHS Hazardous to the aquatic environment (acute) - Category 3 | Japan – GHS Not classified (sufficient information; chemical is not problematic) |
| 13 | Korea – GHS Hazardous to the aquatic environment (acute) - Category 1 [H400 - Very toxic to aquatic life] | | | |
| 14 | New Zealand - GHS 9.1A (algal) - Very ecotoxic in the aquatic environment 9.1A (crustacean) - Very ecotoxic in the aquatic environment 9.1A (fish) - Very ecotoxic in the aquatic environment 9.1A (other) - Very ecotoxic in the aquatic environment | New Zealand - GHS 9.1B (algal) - Ecotoxic in the aquatic environment 9.1B (crustacean) - Ecotoxic in the aquatic environment 9.1B (fish) - Ecotoxic in the aquatic environment 9.1B (other) - Ecotoxic in the aquatic environment environment | New Zealand – GHS 9.1C (algal) -: Harmful to aquatic environment 9.1C (crustacean) -: Harmful to aquatic environment 9.1C (fish) - Harmful to aquatic environment 9.1C (other) - Harmful to aquatic environment | New Zealand - GHS 9.1D (algal) - Slightly harmful in the aquatic environment 9.1D (crustacean) - Slightly harmful in the aquatic environment 9.1D (fish) - Slightly harmful in the aquatic environment 9.1D (other) - Slightly harmful in the aquatic environment |
| 28 | EC - CEPA DSL Inherently Toxic in the Environment | | | |
| Step | II Sources | | | |
| 16 | ECHA C&L Inventory Category Acute 1 | ECHA C&L Inventory Category Acute 2 not implemented | ECHA C&L Inventory Category Acute 3 not implemented | |

| | | Environmental Health: | | |
|------|---------------|--|--|---|
| | Very High (v) | High (H) | Moderate (M) | Low (L) |
| Step | II Sources | | | |
| 17 | N/A | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA ECOTOX, etc. Strong evidence of acute aquatic toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA ECOTOX, etc. Indication of acute aquatic toxicity | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA ECOTOX, etc. Indication of no acute aquatic toxicity |
| 19 | | Technical Criteria 96 hr LC ₅₀ (f) >1 but≤ 10 mg/l 48 hr EC ₅₀ (c) > 1 but≤ 10 mg/l 72 or 96 ErC ₅₀ (a) > 1 but≤ 10 mg/l | Technical Criteria 96 hr LC ₅₀ (f) > 10 but≤ 100 mg/l 48 hr EC ₅₀ (c) > 10 but≤ 100 mg/l 72 or 96 ErC ₅₀ (a) > 10 but≤ 100 mg/l | Technical Criteria 96 hr LC ₅₀ (f) > 100 mg/l 48 hr EC ₅₀ (c) > 100 mg/l 72 or 96 ErC ₅₀ (a) > 100 mg/l |

| | | Environn | nental Fate: Persisten | ce | |
|------|---|---|------------------------|---------|---------------|
| | Very High (v) | High (H) | Moderate (M) | Low (L) | Very Low (vL) |
| Step | Sources | | | • | |
| # | Priority Sources | | | | |
| 3 | EU - SVHC Authorisation List PBT - Banned unless Authorised PBT - Candidate list PBT - Prioritized for listing vPvB - Candidate list vPvB - Banned unless Authorised vPvB - Prioritized for listing | | | | |
| 25 | OSPAR - Priority PBTs & EDs & equivalent concern PBT - Chemical for Priority Action | OSPAR - Priority PBTs & EDs & equivalent concern PBT - Substance of Possible Concern PBT - Substance of Possible Concern (Sections B&C) | | | |
| 29 | US EPA - Priority PBTs (NWMP) Priority PBT | | | | |
| 30 | US EPA Priority PBTs (PPT) Priority PBT | | | | |
| 31 | US EPA - Toxics Release Inventory PBTs PBT | | | | |

 $^{^{15}}$ f = fish 16 c = crustacea 17 a = algae or other aquatic plants

| | Environmental Fate: Persistence Very High (v) High (H) Moderate (M) Low (L) Very Low (vL) | | | | | | | | | | | | | |
|--------|---|--|---|---|--|--|--|--|--|--|--|--|--|--|
| | Very High (v) | High (H) | Moderate (M) | Low (L) | Very Low (vL) | | | | | | | | | |
| Step I | Sources | | | | | | | | | | | | | |
| # | Priority Sources | | | | | | | | | | | | | |
| 32 | EU - ESIS PBT Fulfills PBT Criteria - Action Deferred PBT POP (Persistent Organic Pollutant) vPvB PBT & POP PBT & vPvB PBT & vPvB PBT & vPvB & POP Under PBT evaluation | | | | | | | | | | | | | |
| 33 | UNEP Stockholm Conv - Persistent Organic Pollutants Priority POP Persistent Organic Pollutant (POP) - under review | | | | | | | | | | | | | |
| # | Secondary Sources | | | | | | | | | | | | | |
| 23 | ChemSec - SIN List PBT / vPvB (Persistent, Bioaccumulative, & Toxic / very Persistent & very Bioaccumulative) | | | | | | | | | | | | | |
| 28 | EC - CEPA DSL Persistent Persistent, Bioaccumulative and inherently Toxic (PBiTH) to humans Persistent, Bioaccumulative and inherently Toxic (PBiTE) to the Environment (based on aquatic organisms) | | | | | | | | | | | | | |
| 34 | WA DoE - PBT PBT | | | | | | | | | | | | | |
| 35 | OR DEQ - Priority Persistent Pollutants Priority Persistent Pollutant - Tier 1 Priority Persistent Pollutant - Tier 2 Legacy Persistent Pollutants | | | | | | | | | | | | | |
| Step I | I Sources | | | | | | | | | | | | | |
| 17 | N/A | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Strong evidence of persistence | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Indication of persistence | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Indication of no persistence Meets GHS Definition for Rapid Degradability | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Indication of no persistence Meets 10-day window as measured in a ready biodegradation | | | | | | | | | |

| | | Environn | nental Fate: Persistend | e | |
|------|--|---|---|--|---------------|
| | Very High (v) | High (H) | Moderate (M) | Low (L) | Very Low (vL) |
| Step | II Sources | | | | |
| 19 | Technical Criteria Half-life (ss ¹⁸) > 180 days Half-life (w ¹⁹) > 60 days Half-life (a ²⁰) > 5 days | Technical Criteria Half-life (ss) > 60 to 180 days Half-life (w) > 40 to 60 days Half-life (a ²¹) > 2 to 5 days Evidence for long-range environmental transport | Technical Criteria Half-life (ss) > 16 to 60 days Half-life (w) > 16 to 40 days Suggestive evidence for long- range environmental transport | Technical Criteria Half-life (ss) < 16 days Half-life (w) < 16 days Half-life (a) < 2 days | |

| | | Environm | ental Fate: Bioaccumu | ılation | |
|------|---|---|-----------------------|---------|---------------|
| | Very High (v) | High (H) | Moderate (M) | Low (L) | Very Low (vL) |
| Step | I Sources | | | | |
| # | Priority Sources | | | | |
| 3 | EU - SVHC Authorisation List PBT - Banned unless Authorised PBT - Candidate list PBT - Prioritized for listing vPvB - Candidate list vPvB - Banned unless Authorised vPvB - Prioritized for listing | | | | |
| 25 | OSPAR - Priority PBTs & EDs & equivalent concern PBT - Chemical for Priority Action | OSPAR - Priority PBTs & EDs & equivalent concern PBT - Substance of Possible Concern PBT - Substance of Possible Concern (Sections B&C) | | | |
| 29 | US EPA - Priority PBTs (NWMP) Priority PBT | | | | |
| 30 | US EPA Priority PBTs (PPT) Priority PBT | | | | |
| 31 | US EPA - Toxics Release Inventory PBTs PBT | | | | |

 $^{^{18}}$ ss = soil or sediment 19 w = water 20 a = air 21 a = air

| | Environmental Fate: Bioaccumulation Very High (v) High (H) Moderate (M) Low (L) Very Low (vL) | | | | | | | | | | | | | |
|------|--|---|--|--|---|--|--|--|--|--|--|--|--|--|
| | Very High (v) | High (H) | Moderate (M) | Low (L) | Very Low (vL) | | | | | | | | | |
| Step | l Sources | | | | | | | | | | | | | |
| # | Priority Sources | | | | | | | | | | | | | |
| 32 | EU - ESIS PBT Fulfills PBT Criteria - Action Deferred PBT POP (Persistent Organic Pollutant) vPvB PBT & POP PBT & vPvB PBT & vPvB PBT & vPvB & POP Under PBT evaluation | | | | | | | | | | | | | |
| 33 | UNEP Stockholm Conv - Persistent Organic Pollutants Priority POP Persistent Organic Pollutant (POP) - under review | | | | | | | | | | | | | |
| # | Secondary Sources | | | | | | | | | | | | | |
| 23 | ChemSec - SIN List PBT / vPvB (Persistent, Bioaccumulative, & Toxic / very Persistent & very Bioaccumulative) | | | | | | | | | | | | | |
| 28 | EC - CEPA DSL Bioaccumulative Persistent, Bioaccumulative and inherently Toxic (PBiTH) to humans Persistent, Bioaccumulative and inherently Toxic (PBiTE) to the Environment (based on aquatic organisms) | | | | | | | | | | | | | |
| 34 | WA DoE - PBT | | | | | | | | | | | | | |
| | II Sources | | | | | | | | | | | | | |
| 17 | N/A | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Strong evidence of bioaccumulation | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Indication of bioaccumulation | EU RA, IUCLID Datasheet, RTECS, HSDB, UNEP SIDS, OSHA, Danish Q(SAR), US EPA PBT Profiler, etc. Indication of no bioaccumulation | | | | | | | | | | |
| 19 | Technical Criteria BCF/BAF $\geq 5,000$ Log $K_{ow}^{22} \geq 5$ | $\label{eq:controller} \begin{split} \textbf{Technical Criteria} \\ BCF/BAF &\geq 1,000 \text{ but } < 5,000 \\ Log \ K_{ow} &\geq 4.5 \text{ but } < 5 \\ Weight of evidence-presence in humans \& wildlife \end{split}$ | $\label{eq:controller} \begin{split} \textbf{Technical Criteria} & BCF/BAF \geq 500 \text{ but} < 1,000 \\ Log \ K_{ow} \geq 4 \text{ but} < 4.5 \\ Suggestive evidence-presence in humans & wildlife \end{split}$ | Technical Criteria BCF/BAF ≥ 100 but < 500 | Technical Criteria: BCF/BAF < 100 Log K _{ow} < 4 | | | | | | | | | |

[.]

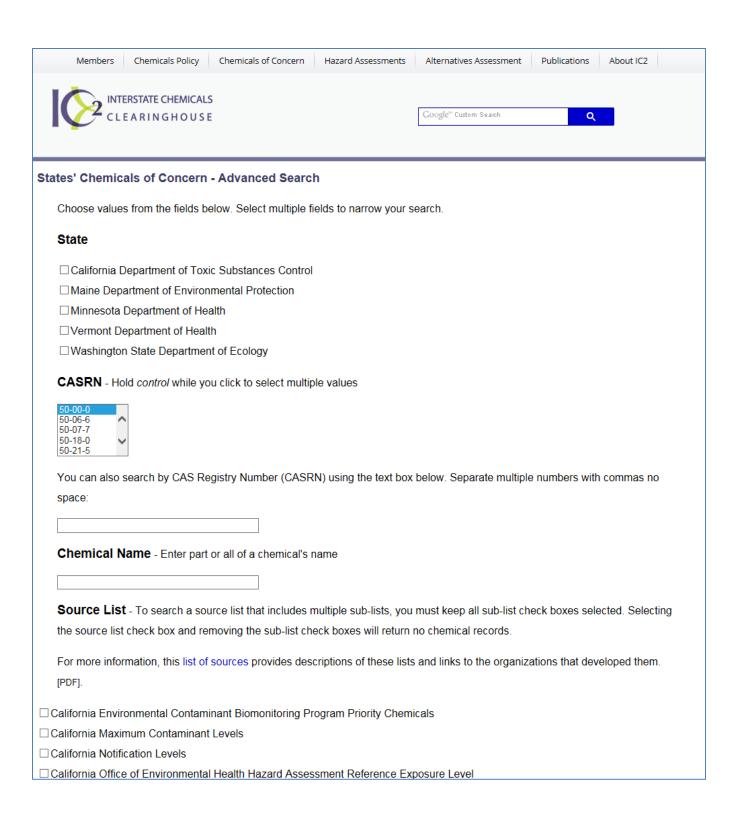
 $^{^{22}}$ Log K_{ow} = logarithm of the octanol/water partition coefficient

Appendix 9: The Interstate Chemicals Clearinghouse (IC2) States' Chemicals of Concern

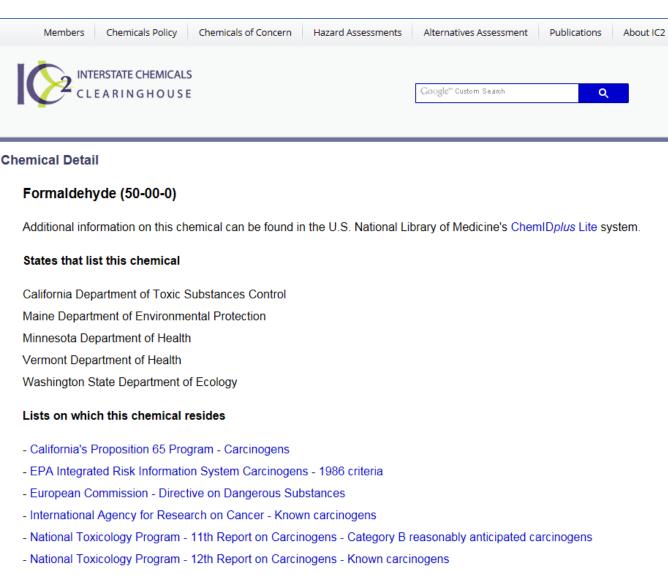
Appendix 9 contains an additional source of data, the Interstate Chemicals Clearinghouse States' Chemicals of ConcernDatabase, and information on individual authoritative Step I sources in case the user would like to go directly to the source data. Ecology does not recommend users visit individual sites as the data are more readily available in automated sources such as Pharos and ChemHAT.

One objective of the IC2 is to share data and resources among members. To meet this goal, the IC2 created a database of all of the chemicals of concern identified by five member states (California, Maine, Minnesota, Vermont, and Washington). This database is freely available to anyone with access to the internet. As an alternative to some of the ListTranslator sources such as Pharos and ChemHAT, this database may be searched for information on specific chemicals. Caution: Unlike Pharos and QCAT, this database is not routinely updated; therefore, it may not contain the most recent information or changes to the source lists.

Initial access to the IC2 States' Chemicals of Concern Database appears as follows:



The IC2 database allows users to search for specific chemicals, browse by CAS or see lists created by individual states. Using formaldehyde (CAS 50-00-0) as an example, the data for the CASRN was selected and submitted:



- California Notification Levels
- California Toxic Air Contaminants
- California Office of Environmental Health Hazard Assessment Reference Exposure Level

This information is similar to what was found in other databases although additional information is provided as well. The report shows on which states lists the chemical appears and the sources that identified it as a chemical of concern. The information pertinent to a QCAT assessment includes:

- 1. Carcinogen (Prop 65)
- 2. Carcinogen (EPA IRIS)
- 3. Known Carcinogen (IARC)
- 4. Category B 'reasonably anticipated carcinogen' (NTP)

This data can be used to assign a carcinogenicity rank for formaldehyde. The QCAT user should note the source and date this information was obtained and proceed with the QCAT assessment.

Appendix 10: Checklist

This checklist identifies the individual sources for both Step I and Step II sources and provides links to the individual sources. The assessor may also print out the checklist and use it to verify review of all the pertinent data sources used to conduct an alternatives assessment.

| | Step I: Priority Sources | | | | | | | | | | | | | | | | | | |
|----|--|---|---|---|---|---|-----------|----|---|-----|-----|-----|-----|----|----|----|---|-----------|------|
| | Sources | С | М | R | D | Ε | AT | ST | Ν | SnS | SnR | Irs | IrE | AA | CA | Eo | Р | В | Ex F |
| 1 | US NIH – Report on Carcinogens | | | | | | | | | | | | | | | | | | |
| 2 | CA EPA – Prop 65 | | | | | | | | | | | | | | | | | | |
| 3 | ECHA – SVHC Authorisation List | | | | | | | | | | | | | | | | | | |
| 4 | US CDC – Occupational Carcinogens | | | | | | | | | | | | | | | | | | |
| 5 | IARC | | | | | | | | | | | | | | | | | | |
| 6 | US EPA – IRIS Carcinogens | | | | | | | | | | | | | | | | | | |
| 7 | EU Annex VI CMRs | | | | | | | | | | | | | | | | | | |
| 8 | EU – GHS (H Statements) | | | | | | $\sqrt{}$ | | | | | | | | | | | | |
| 9 | EU – REACH Annex XVII CMRs | | | | | | | | | | | | | | | | | | |
| 10 | EU – R-Phrases | | | | | | $\sqrt{}$ | | | | | | | | | | | | |
| 11 | German MAK list | | | | | | | | | | | | | | | | | | |
| 18 | US NIH – Repro. & Dev. Monographs | | | | | | | | | | | | | | | | | | |
| 25 | OSPAR – Priority PBTs & EDs ¹ | | | | | | | | | | | | | | | | | | |
| 26 | US EPA – EPCRA Extr. Haz. Subst. | | | | | | | | | | | | | | | | | | |
| 27 | Quebec CSST-WHMIS 1998 | | | | | | $\sqrt{}$ | | | | | | | | | | | | |
| 29 | US EPA – Priority PBTs (NWMP) | | | | | | | | | | | | | | | | | $\sqrt{}$ | |
| 30 | US EPA – Priority PBTs (PPT) | | | | | | | | | | | | | | | | | | |
| 31 | US EPA – Toxics Release Invent. PBTs | | | | | | | | | | | | | | | | | $\sqrt{}$ | |
| 32 | EU – ESIS PBT | | | | | | | | | | | | | | | | | $\sqrt{}$ | |
| 33 | UNEP Stockholm Conv–Pers. Org. Pol. | | | | | | | | | | | | | | | | | $\sqrt{}$ | |

| | Step I: Secondary Sources | | | | | | | | | | | | | | | | | | | |
|----|--|-----------|-----------|---|-----------|-----------|-----------|----|---|-----|-----|-----|-----|-----------|----|----|-----------|---|----|---|
| | Sources | С | М | R | D | Ε | AT | ST | N | SnS | SnR | Irs | IrE | AA | CA | Eo | Р | В | Ex | F |
| 12 | Japan – GHS | $\sqrt{}$ | | | | | V | | | | | | | | | | | | | |
| 13 | Korean – GHS | $\sqrt{}$ | $\sqrt{}$ | | $\sqrt{}$ | | $\sqrt{}$ | | | | | | | $\sqrt{}$ | | | | | | |
| 14 | New Zealand – GHS | $\sqrt{}$ | | | $\sqrt{}$ | | | | | | | | | | | | | | | |
| 19 | Boyes – Neurotoxicants | | | | $\sqrt{}$ | | | | | | | | | | | | | | | |
| 20 | G&L Neurotoxic Chemicals | | | | $\sqrt{}$ | | | | | | | | | | | | | | | |
| 21 | EU – Priority Endocrine Disruptors | | | | | $\sqrt{}$ | | | | | | | | | | | | | | |
| 22 | OSPAR – Priority PBTs & EDs ² | | | | | $\sqrt{}$ | | | | | | | | | | | | | | |
| 23 | ChemSec – SIN List | | $\sqrt{}$ | | $\sqrt{}$ | $\sqrt{}$ | | | | | | | | $\sqrt{}$ | | | $\sqrt{}$ | | | |
| 24 | TEDX – Potential Endocrine Disruptors | | | | | $\sqrt{}$ | | | | | | | | | | | | | | |
| 28 | EC – CEPA DSL | | | | | | | | | | | | | | | | $\sqrt{}$ | | | |
| 34 | WA DoE - PBT | | | | | | | | | | | | | | | | | | | |
| 35 | OR DEQ – Priority Persistent Pollutants | | | | | | | | | | | | | | | | V | | | |

| | Step II: Sources | | | | | | | | | | _ | | | | | - | | | | |
|-----|-----------------------------------|-----------|---|---|----------|---|----------|----|---|-----|-----|-----|-----|----|----|----|---|---|----|---|
| | Sources | С | М | R | D | Ε | AT | ST | Ν | SnS | SnR | Irs | IrE | AA | CA | Eo | Р | В | Ex | F |
| 15 | ISSCAN Value | $\sqrt{}$ | | | | | | | | | | | | | | | | | | |
| 16 | ECHA C&L Inventory | V | | | V | | V | | | | | | | | | | | | | |
| 17a | EU Risk Assessments | | | | | | | | | | | | | | | | | | | |
| 17b | RTECS ³ | | | | | | | | | | | | | | | | | | | |
| 17c | Hazardous Subst. Data Bank (HSDB) | | | | | | √ | | | | | | | | | | | | | |
| 17d | UNEP SIDS | V | | | V | | V | | | | | | | | | | | | | |
| 17e | OSHA – Occupational Chemical DB | V | | | | | | | | | | | | | | | | | | |
| 17f | Danish (Q)SAR Database | | | | | | √ | | | | | | | | | | | | | |
| 17g | US EPA ECOTOX Database | | | | | | | | | | | | | | | | | | | |
| 17h | US EPA PBT Profiler | | | | | | | | | | | | | | | | | | | |
| 36 | US EPA Characterization Criteria⁴ | | | | | | | | | | | | | | | | | | | |

- 1 PBT listings only
- 2 ED listings only
- 3 RTECS is provided by many users, all of which charge a fee for its use.
 - EPA's New Chemical Program established these criteria to assign a level of concern and are used by EPA's Design for the Environment Program
- 4 to assign a level of concern while conducting a chemical hazard assessment. They were subsequently incorporated into the GreenScreen and QCAT methodologies.

| = GreenScreen criteria not used in QCAT |
|--|
| = GreenScreen criteria used in QCAT |
| = Data for this endpoint COULD be found in Source |

| Link | <u>s</u> | | | | |
|------|--|--|--|--|--|
| 1 | http://ntp.niehs.nih.gov/pubhealth/roc/index.html | | | | |
| 2 | http://oehha.ca.gov/prop65/prop65_list/Newlist.html | | | | |
| 3 | http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification | | | | |
| 4 | http://www.cdc.gov/niosh/topics/cancer/npotocca.html | | | | |
| 5 | http://monographs.iarc.fr/ENG/Classification/index.php | | | | |
| 6 | http://www2.epa.gov/iris | | | | |
| 7 | http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database | | | | |
| 8 | http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database | | | | |
| 9 | http://echa.europa.eu/en/addressing-chemicals-of-concern/restrictions/list-of-restrictions | | | | |
| 10 | http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database | | | | |
| 11 | http://onlinelibrary.wiley.com/book/10.1002/3527600418/ | | | | |
| 12 | http://www.safe.nite.go.jp/english/ghs/ghs_index.html#results | | | | |
| 13 | http://ncis.nier.go.kr/ | | | | |
| 14 | http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx | | | | |
| 15 | http://www.iss.it/meca/index.php?lang=1&id=199&tipo=25 | | | | |
| 16 | http://echa.europa.eu/information-on-chemicals/cl-inventory-database | | | | |
| 17a | http://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation | | | | |
| 17b | http://ccinfoweb.ccohs.ca/rtecs/search.html | | | | |
| 17c | http://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm | | | | |
| | | | | | |

- 17d http://webnet.oecd.org/hpv/ui/Search.aspx
- 17e https://www.osha.gov/chemicaldata/
- 17f http://eng.mst.dk/topics/chemicals/assessment-of-chemicals/the-advisory-list-for-selfclassification/
- 17g https://cfpub.epa.gov/ecotox/quick_query.htm
- 17h http://www.pbtprofiler.net/
- 18 http://ntp.niehs.nih.gov/pubhealth/hat/index.html
- http://onlinelibrary.wiley.com/doi/10.1002/0471435139.tox025.pub2/abstract
- www.fundrogertorne.org/salud-infancia-medio-ambiente/pdf/developmental-neurotoxicity-of-industrial-chemicals-grandjean-landrigan.pdf
- 21 http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list
- http://www.ospar.org/work-areas/hasec/chemicals
- 23 http://sinlist.chemsec.org/
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- http://www.ecfr.gov/cgi-bin/text-idx?SID=dfa8e582c4ff253425fbbc86e27ac6f8&node=pt40.28.355&rgn=div5
- 27 http://www.csst.qc.ca/en/prevention/reptox/Pages/list-whmis-1988-a.aspx
- 28 http://www.ec.gc.ca/CEPARegistry/subs_list/dsl/dslsearch.cfm
- 29 http://www.epa.gov/epawaste/hazard/wastemin/priority.htm
- 30 https://www3.epa.gov/region9/waste/p2/projects/pbts.html
- 31 http://www2.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri
- 32 http://echa.europa.eu/information-on-chemicals/pbt-vpvb-assessments-under-the-previous-eu-chemicals-legislation
- 33 http://chm.pops.int/Convention/ThePOPs/tabid/673/language/en-US/Default.aspx
- http://apps.leg.wa.gov/WAC/default.aspx?cite=173-333-310
- 35 http://www.deq.state.or.us/wq/SB737
- 36 https://www.epa.gov/saferchoice/alternatives-assessment-criteria-hazard-evaluation

Appendix 11: QCAT Abbreviations

| а | = | Air |
|------------------|---|--|
| AA | = | Acute Aquatic Toxicity or |
| AA | = | Alternatives Assessment |
| AT | = | Acute Mammalian Toxicity |
| В | = | Bioaccumulation |
| BAF | = | Bioaccumulation factor |
| BCF | = | Bioconcentration factor |
| B _i T | = | Chemicals that are bioaccumulative AND inherently toxic |
| BM | = | Benchmark |
| bw/d | = | Body weight per day |
| С | = | Carcinogenicity |
| CA | Ш | Chronic Aquatic Toxicity |
| CAS Number | П | Chemical Abstract Service Number; uniquely identifier for chemicals |
| CDC | П | Centers for Disease Control and Prevention |
| СНА | П | Chemical Hazard Assessment |
| ChV | П | Chronic Value for fish toxicity (Chronic aquatic toxicity is not part of QCAT. Value NOT used.) |
| CLP | П | Classification and labelling program |
| CMR | П | Chemicals that are carcinogenic, mutagenic and/or reproductive toxic |
| D | = | Developmental Toxicity |
| DfE | П | US EPA Design for the Environment program |
| dm | = | Dust or mist |
| DSL | = | Domestic substances list; Canadian legislation |
| E | = | Endocrine Activity |
| EC | = | European Commission; Executive body of the European Union |
| EC ₅₀ | = | Effective concentration of substance that caused 50% of the population to die |
| ECHA | = | European Chemicals Agency; Agency formed to implement the REACH legislation in the EU |
| Ecotox | = | Eco-toxicological hazard endpoints |
| EPA | = | US Environmental Protection Agency |
| EPCRA | = | Emergency Planning and Community Right-to-Know Act; US legislation |

| | l | |
|---------------------|---|---|
| ErC ₅₀ | = | EC ₅₀ in terms of reduction of growth rate |
| ESIS | = | European chemical Substances Information System (database no longer supported by ECHA) |
| EU | = | European Union |
| F | = | Flammability |
| g | = | Gas |
| German MAK | = | German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) |
| GHS | = | Globally Harmonized System of Classification and Labelling of Chemicals |
| Grade | = | Level of toxicity concern for the chemical based upon the QCAT grading methodology |
| GreenScreen | = | GreenScreen for Safer Chemicals; a CHA methodology based upon EPA DfE work |
| Group I | = | Priority human hazard toxicology endpoints |
| Group II | = | Important human hazard toxicology endpoints with four levels of concern |
| Group II* | = | Important human hazard toxicology endpoints with three levels of concern |
| GS | = | GreenScreen |
| HH1 | = | Human Health Group 1 hazard endpoints (C, M/G, R, D, E) |
| HH2 | = | Human Health Group 2 hazard endpoints (AT) |
| HSDB | = | Hazardous substances databank |
| HSNO | = | Hazardous Substances and New Organisms; New Zealand legislation |
| IARC | = | International Agency for Research on Cancer |
| IrE | = | Irritation-Eye |
| IrS | = | Irritation-Skin |
| ISSCAN | = | Istituto Superiore di Sanita list of chemical carcinogens, modelling results |
| i T | = | Chemicals toxic to <u>either</u> humans or the environment (i.e. inherently toxic) |
| IUCLID | = | International uniform chemical information database |
| Japan METI/MOE | = | Japan's Ministry of Economy, Trade and Industry (METI) and Ministry of the Environment (MOE) |
| Korean NIER | = | Korean National Institute of Environmental Research (NIER) |
| LC ₅₀ | = | Concentration at which 50% of test animals died after exposure |
| LD ₅₀ | = | Dose at which 50% of test animals died during exposure; |
| LOAEL | = | Lowest observed adverse effect level |
| log K _{ow} | = | Log of the octanol water partition coefficient; used as surrogate to evaluate bioaccumulation |
| М | = | Mutagenicity/Genotoxicity |
| | | |

| mg/kg | = | Milligrams per kilogram (aka ppm) |
|-------------------|---|--|
| mg/L | = | Milligrams per Liter (aka ppm) |
| MSDS | = | Material Safety Data Sheet |
| N | Ш | Neurotoxicity |
| N/A | Ш | 'Not applicable' |
| NIH | Ш | US National Institute of Health |
| NOEC | Ш | No observed effect concentration |
| NTP | = | National Toxicology Program |
| OECD | = | Organization for Economic Cooperation and Development |
| Oregon P3 | = | Oregon list of persistent priority pollutants |
| OSHA | = | Occupation Safety and Health Administration |
| OSPAR | Ш | Oslo Paris Convention of POPs |
| Р | = | Persistence |
| PB _i T | = | Chemicals that are persistent, bioaccumulative AND inherently toxic |
| PBT | = | Chemicals that are persistent, bioaccumulative AND toxic |
| P _i T | = | Chemicals that are persistent AND inherently toxic |
| POP | = | Persistent Organic Pollutants |
| QCAT | = | Quick Chemical Assessment Tool |
| R | = | Reproductive Toxicity |
| RA | = | Risk assessment |
| REACH | = | Registration, Evaluation & Authorisation of Chemicals; EU legislation |
| Repeat | Ш | Repeat dose or exposure |
| RTECS | Ш | Registry of toxic effects of chemical substances |
| Rx | Ш | Reactivity |
| SDS | Ш | Safety Data Sheet |
| SIDS | Ш | Safety information datasheet |
| Single | Ш | Single dose or exposure |
| SnR | Ш | Sensitization-Respiratory |
| SnS | = | Sensitization-Skin |
| SS | = | Soil or sediment |
| ST | = | Systemic toxicity |
| | | |

| SVHC | = | Substances of very high concern (part of REACH legislation) |
|------------------|---|--|
| TC _{lo} | = | Toxic concentration low: Lowest concentration of a substance in air that has produced any toxic effect in humans or produced tumorigenic or reproductive effects in animals. |
| TD _{lo} | Ш | Toxic dose low: Lowest dose of a substance introduced by any route, other than inhalation, reported to produce any toxic effect in humans or to produce tumorigenic or reproductive effects in animals. |
| TRI | = | Toxics Release Inventory; US legislation |
| UNEP | = | United Nations Environment Programme |
| v | = | Vapor |
| vPvT | = | Chemicals that are very persistent AND very toxic |
| w | = | Water |
| WA DoE | = | Washington State Department of Ecology |